

US3812059 (Prod: Sundance Clinical Research - Platinum - PPDS)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:55:19

All time stamps listed in this document are displayed in GMT

US3812059

Form: Participant Creation

Generated On: 26 Nov 2020 09:55:19

[Participant ID](#)

US3812059

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

US3812059

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:55:19

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	06 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

US3812059

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:19

Date of Birth (MMM yyyy)	(b) (6) 1999
Age	20
Age Units	YEARS
Age (Derived)	20
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
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

US3812059

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:55:19

Date of Informed Consent (<i>dd MMM yyyy</i>)	06 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☒
	Amendment 2 ☐
	Amendment 3 ☐
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

US3812059

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:55:19

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3812059

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:55:19

Were any significant conditions reported?

Yes ☒

No ☐

US3812059

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:55:19

Condition	LEFT EYE GLAUCOMA
Start date (dd MMM yyyy)	(b) (6) 1999
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	(b) (6) 1999
Start Year (derived)	1999
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3812059

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:55:19

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3812059

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:55:19

Condition	ATROPINE ALLERGY
Start date (dd MMM yyyy)	(b) (6) 1999
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	(b) (6) 1999
Start Year (derived)	1999
Stop Month and Year (derived)	
Stop Year (derived)	

US3812059

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:55:19

Condition	FREQUENT HEADACHES
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

US3812059

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:55:19

Condition	VAPE SMOKER
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3812059

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:55:19

Condition	LEFT EYE SHUNT REVISION X18
Start date (dd MMM yyyy)	(b) (6) 1999
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	(b) (6) 1999
Start Year (derived)	1999
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

US3812059

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:55:19

Condition	(B) EYELID RETRACTION
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☒
	No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3812059

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:55:19

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3812059

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:55:19

Condition	NICOTINE ADDICTION
Start date (dd MMM yyyy)	UN JAN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)	

US3812059

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:55:19

Condition	MARIJUANA ABUSE
Start date (dd MMM yyyy)	UN FEB 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3812059

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:55:19

Condition	POST TRAUMATIC STRESS DISORDER
Start date (dd MMM yyyy)	UN JAN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)	

US3812059

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:55:19

Condition	ALCOHOL USE DISORDER
Start date (dd MMM yyyy)	UN JAN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)	

US3812059

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	06 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	09:30 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 09:30
Height (<i>xxx.x</i>)	64.8 in
Weight (<i>xxx.x</i>)	137 lb
BMI (<i>xxx.x</i>)	22.98690 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3812059

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:55:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 AUG 2020

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

US3812059

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:55:19

Date of assessment (*dd MMM yyyy*) 06 AUG 2020

Is the participant of childbearing potential? Yes ☒ No ☐

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

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

Date of last menstruation unknown False

US3812059

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:19

Was the pregnancy test performed?	Yes ☒
	No ☐
Date of test (<i>dd MMM yyyy</i>)	06 AUG 2020
Test performed	Urine ☒
	Serum ☐
Result	Positive ☐
	Negative ☒
Was FSH sample collected?	Yes ☐
	No ☒
Collection date	
Collection time	
Collection date and time (derived)	

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:19

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

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:19

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

US3812059

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:55:19

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	06 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

US3812059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:55:19

What was the date of randomization? (dd MMM yyyy) 06 AUG 2020

What was the participant's randomization number? 101557

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 ☒

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:55:19

Height	ND - Not Done
Weight	ND - Not Done

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:19

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	06 AUG 2020
Time of assessment (00:00-23:59)	09:30 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 09:30
Temperature (xxx.x)	98.2 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	101 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:19

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	06 AUG 2020
Time of assessment (00:00-23:59)	11:30 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 11:30
Temperature (xxx.x)	98.2 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

US3812059

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:55:19

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.

US3812059

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:19

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed _____ Urine ☐

Serum ☐

Result _____ Positive ☐

Negative ☐

Was FSH sample collected? Yes ☐

No ☐

Collection date _____

Collection time _____

Collection date and time (derived) _____

US3812059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:55:19

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)	06 AUG 2020
What was the treatment time? (00:00-23:59)	10:57 (24 HR)
Treatment Date and Time (derived)	06 AUG 2020 10:57
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

US3812059

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:19

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	06 AUG 2020
Collection time (<i>00:00-23:59</i>)	10:35 (24 HR)
Collection date and time (derived)	06 AUG 2020 10:35

US3812059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:55:19

Collection date (<i>dd MMM yyyy</i>)			06 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:38	06 AUG 2020 10:38
Nasopharyngeal Swab 2	No		

US3812059

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:55:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 11:36

PC Open Date & Time

06 AUG 2020 11:17

PC Close Date & Time

06 AUG 2020 13:47

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

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 99.3 °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	06 AUG 2020 23:15
PC Open Date & Time	06 AUG 2020 14:42
PC Close Date & Time	07 AUG 2020 11:59

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:55:19

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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 22:32

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:55:19

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

99.0 °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

08 AUG 2020 22:25

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:55:19

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

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 18:19

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:55:19

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

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 22:26

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:55:19

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

98.9 °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

12 AUG 2020 08:59

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:55:19

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

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

12 AUG 2020 19:57

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 AUG 2020 11:37

PC Open Date & Time

06 AUG 2020 11:17

PC Close Date & Time

06 AUG 2020 13:47

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

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

06 AUG 2020 23:10

PC Open Date & Time

06 AUG 2020 14:42

PC Close Date & Time

07 AUG 2020 11:59

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:55:19

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

07 AUG 2020 22:26

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:55:19

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

08 AUG 2020 21:57

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:55:19

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

09 AUG 2020 17:38

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:55:19

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

10 AUG 2020 19:15

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:55:19

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

11 AUG 2020 15:06

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:55:19

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

12 AUG 2020 19:55

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

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

No ☒

Yes ☐

PC Time stamp	06 AUG 2020 11:38
PC Open Date & Time	06 AUG 2020 11:17
PC Close Date & Time	06 AUG 2020 13:47

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

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

No ☒

Yes ☐

PC Time stamp	06 AUG 2020 23:09
PC Open Date & Time	06 AUG 2020 14:42
PC Close Date & Time	07 AUG 2020 11:59

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:55:19

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 ☒

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:55:19

Yes ☐	
PC Time stamp	07 AUG 2020 21:51
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:55:19

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 ☒

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:55:19

Yes ☐	
PC Time stamp	08 AUG 2020 21:57
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:55:19

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 ☒

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:55:19

Yes ☐	
PC Time stamp	09 AUG 2020 17:37
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:55:19

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 ☒

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:55:19

Yes ☐	
PC Time stamp	10 AUG 2020 19:15
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:55:19

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 ☒

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:55:19

Yes ☐	
PC Time stamp	11 AUG 2020 15:06
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:55:19

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 ☒

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:55:19

Yes ☐	
PC Time stamp	12 AUG 2020 19:55
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3812059

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

13 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812059

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812059

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812059

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812059

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812059

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812059

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:55:19

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	01 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:19

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	01 SEP 2020
Time of assessment (00:00-23:59)	14:36 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 14:36
Temperature (xxx.x)	97.4 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:19

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	01 SEP 2020
Time of assessment (00:00-23:59)	15:47 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 15:47
Temperature (xxx.x)	98.3 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3812059

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:55:19

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.

US3812059

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:19

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

US3812059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:55:19

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)	01 SEP 2020
What was the treatment time? (00:00-23:59)	15:09 (24 HR)
Treatment Date and Time (derived)	01 SEP 2020 15:09
Which arm was used to give treatment?	Left Arm ☒
	Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3812059

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:19

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	01 SEP 2020
Collection time (<i>00:00-23:59</i>)	14:55 (24 HR)
Collection date and time (derived)	01 SEP 2020 14:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:55:19

Collection date (<i>dd MMM yyyy</i>)			01 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:58	01 SEP 2020 14:58
Nasopharyngeal Swab 2	No		

US3812059

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

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

98.3 °F

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

Yes ☐
No ☒

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

PC Time Stamp 01 SEP 2020 15:44

PC Open Date & Time 01 SEP 2020 15:29

PC Close Date & Time 01 SEP 2020 17:59

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

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

98.4 °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	02 SEP 2020 00:52
PC Open Date & Time	01 SEP 2020 18:54
PC Close Date & Time	02 SEP 2020 11:59

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:55:19

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 08:58

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:55:19

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

98.5 °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

03 SEP 2020 23:51

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:55:19

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

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 09:53

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:55:19

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

98.9 °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

05 SEP 2020 23:11

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:55:19

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

99.3 °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

06 SEP 2020 20:49

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:55:19

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

99.0 °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

07 SEP 2020 23:41

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 15:44

PC Open Date & Time

01 SEP 2020 15:29

PC Close Date & Time

01 SEP 2020 17:59

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

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

02 SEP 2020 00:53

PC Open Date & Time

01 SEP 2020 18:54

PC Close Date & Time

02 SEP 2020 11:59

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:55:19

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

03 SEP 2020 08:57

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:55:19

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

03 SEP 2020 23:51

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:55:19

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

05 SEP 2020 09:53

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:55:19

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

05 SEP 2020 23:11

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:55:19

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

06 SEP 2020 20:48

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:55:19

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

07 SEP 2020 21:33

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 15:44
PC Open Date & Time	01 SEP 2020 15:29
PC Close Date & Time	01 SEP 2020 17:59

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 00:53
PC Open Date & Time	01 SEP 2020 18:54
PC Close Date & Time	02 SEP 2020 11:59

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:55:19

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 ☒

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:55:19

Yes ☐	
PC Time stamp	03 SEP 2020 08:57
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:55:19

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 ☒

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:55:19

Yes ☐	
PC Time stamp	03 SEP 2020 23:50
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:55:19

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 ☒

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:55:19

Yes ☐	
PC Time stamp	05 SEP 2020 09:53
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:55:19

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 ☒

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:55:19

Yes ☐	
PC Time stamp	05 SEP 2020 23:11
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:55:19

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 ☒

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:55:19

Yes ☐	
PC Time stamp	06 SEP 2020 20:48
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:55:19

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 ☒

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:55:19

Yes ☐	
PC Time stamp	07 SEP 2020 21:33
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3812059

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

08 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812059

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812059

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812059

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812059

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812059

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812059

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:55:19

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	30 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3812059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	30 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	15:56 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 15:56
Temperature (<i>xxx.x</i>)	98.1 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	92 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	60 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3812059

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:55:19

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.

US3812059

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:19

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	30 SEP 2020
Collection time (<i>00:00-23:59</i>)	16:10 (24 HR)
Collection date and time (derived)	30 SEP 2020 16:10

US3812059

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 11:35:30

Patient Cloud Open Date & Time

06 OCT 2020 00:01

Patient Cloud Close Date & Time

10 OCT 2020 23:59

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐
Have 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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	True
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	True
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☒
Please contact your study clinic immediately. Click below to confirm that you have read this 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	13 OCT 2020 22:45:44
Patient Cloud Open Date & Time	13 OCT 2020 00:01
v6.020 DTW (1102)	127 of 2812

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

17 OCT 2020 23:59

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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	23 OCT 2020 23:51:42
Patient Cloud Open Date & Time	20 OCT 2020 00:01
Patient Cloud Close Date & Time	24 OCT 2020 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2020 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2020 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2020 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2020 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2020 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2020 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

DAY 103

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2020 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2020 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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](#)

28 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2020 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2020 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

16 DEC 2020 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2020 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2020 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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°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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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°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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 DEC 2021 00:01
Patient Cloud Close Date & Time	15 DEC 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3812059

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

28 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812059

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812059

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:19

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

US3812059

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:19

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:55:19

Date of Contact	08 OCT 2020
Time of Contact	16:59
Date and Time of Contact (derived)	08 OCT 2020 16:59
Type of Contact	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☒
	Safety Call ☐
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☒
	No ☐

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:55:19

Symptom Day

Day 1	☒
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:55:19

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	08 OCT 2020	
Assessment Not Done	False	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	348 of 2812	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:55:19

	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☒

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:55:19

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:55:19

Symptom Day

Day 1	☐
Day 2	☒
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:55:19

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	09 OCT 2020	
Assessment Not Done	False	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	352 of 2812	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:55:19

	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☒

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:55:19

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:55:19

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☒
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:55:19

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	10 OCT 2020	
Assessment Not Done	False	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	356 of 2812	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:55:19

	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☒

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:55:19

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:55:19

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☒
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:55:19

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	11 OCT 2020	
Assessment Not Done	False	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	360 of 2812	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:55:19

	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☒

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:55:19

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:55:19

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☒
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:55:19

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	12 OCT 2020	
Assessment Not Done	False	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	364 of 2812	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:55:19

	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☒

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:55:19

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:55:19

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☒
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:55:19

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	13 OCT 2020	
Assessment Not Done	False	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	368 of 2812	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:55:19

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:55:19

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:55:19

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☒
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:55:19

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	14 OCT 2020	
Assessment Not Done	False	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	372 of 2812	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:55:19

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:55:19

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:55:19

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☒
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:55:19

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	15 OCT 2020	
Assessment Not Done	False	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	376 of 2812	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:55:19

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:55:19

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:55:19

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☒
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:55:19

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	16 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	99.1 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	380 of 2812	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:55:19

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:55:19

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:55:19

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☒
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:55:19

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	17 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	384 of 2812	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:55:19

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:55:19

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:55:19

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☒
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:55:19

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	18 OCT 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	388 of 2812	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:55:19

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:55:19

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:55:19

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☒
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:55:19

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	19 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.7 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	392 of 2812	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:55:19

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:55:19

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:55:19

Date of Visit	16 OCT 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes ☒ No ☐
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes ☐ No ☒
Date of Test	11 OCT 2020
Type of Test Performed	Nasopharyngeal Swab ☒ Nasal Swab ☐ Saliva Test ☐ Other ☐
Other, specify _____	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes ☒ No ☐
If yes, provide lab information below	
Lab/ Institution Test Performed	BJC
CLIA Certified?	Yes ☒ No ☐
COVID-19 Positive (CSA Programming Field Only)	0

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:55:19

[Generate Next COVID-19 Assessment](#)

Yes ☐
No ☒

US3812059

Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 09:55:19

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	18 OCT 2020
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3812059

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:55:19

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	16 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD1

US3812059

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	16 OCT 2020
Time of assessment (00:00-23:59)	17:01 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 17:01
Height (xxx.x)	64.8 in
Weight (xxx.x)	136.7 lb
Temperature (xxx.x)	99.1 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	96 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3812059

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:55:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 OCT 2020

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

US3812059

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:55:19

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

16 OCT 2020

US3812059

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:55:19

Was this visit performed?	Yes ☐
	No ☒

Visit date (dd MMM yyyy)	

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

Folder OID	SICKD28

US3812059

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

Were vital signs assessed?	Yes ☐
	No ☒
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3812059

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:55:19

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.

US3812059

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:55:19

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☐

No ☐

NA (COVID-19 Negative) ☒

Date of Collection

US3812059

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:55:19

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3812059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:19

AEID	
Adverse event	NAUSEA
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)	23 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	23 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False
v6.020 DTW (1102)	407 of 2812

US3812059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:19

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
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)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3812059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:55:19

AEID	
Adverse event	VOMITING
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)	23 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	23 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False
v6.020 DTW (1102)	409 of 2812

US3812059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:55:19

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
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)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

AEID	USA-US111-2020-MRNA-1273-P30 1000006
Adverse event	ANXIETY DISORDER
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	24 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	10 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)	26 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	10 NOV 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	411 of 2812

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

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

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

THIS IS A 21-YEAR-OLD
FEMALE THAT PRESENTED IN
THE ER ON 26OCT2020
PRESENTING
WITH "BIZARRE BEHAVIOR".
REPORTS NOT SLEEPING AND
FEELINGS OF A PANIC ATTACK.
SHE HAS
A HISTORY OF TREATED
ANXIETY AND DEPRESSION.
ALSO, CURRENT LEFT EYE
GLAUCOMA. SHE
REPORTS SOCIAL ALCOHOL
AND MARIJUANA USE.
REPORTS NICOTINE
DEPENDENCE. SHE HAS A
HISTORY OF SEXUAL ASSAULT
IN UNJAN2020 (b) (6)
SHE REPORTED INCREASED
ANXIETY FOR THE FEW DAYS
PRIOR TO THE ER VISIT, WHICH
SHE TRIED TO SELF INCREASE
SERTRALINE FROM 100 MG A
DAY TO 150 MG A DAY. SHE
WAS ULTIMATELY ADMITTED
26OCT2020 FOR THE FEELINGS
OF MANIC AND HAVING AN
IDENTITY CRISIS. SHE DENIED
SUICIDAL OR HOMICIDAL
FEELINGS. PERTINENT LABS
INCLUDE NEGATIVE COVID
PCR; POSITIVE
CANNABINOIDS; AND
ABNORMAL URINE ANALYSIS
(1+ PROTEIN, 1+ KETONES, AND
2+ BLOOD).
WHITE BLOOD CELL COUNT

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

WAS INCREASED, 11.2. SHE
WAS GIVEN ONE DOSE OF
25MG
HYDROXYZINE AND
SERTRALINE WAS
DISCONTINUED. SHE WAS
THOROUGHLY ASSESSED AND
GIVEN A MENTAL STATUS
EXAMINATION. SHE WAS
GIVEN A DIAGNOSIS OF
ANXIETY DISORDER.
SHE WAS DISCHARGED IN
STABLE CONDITION WITH AN
ORDER TO START BUPROPION
XL 150MG
DAILY. SHE WAS ALSO GIVEN
NICOTINE 14 MG
TRANSDERMAL PATCH DAILY
AND NICOTINE
POLACRILEX 2MG GUM EVERY
2 HOURS AS NEEDED FOR
NICOTINE ADDICTION. SHE
AGREED TO A
FOLLOW UP APPOINTMENT
WITH PSYCHIATRY ON
16NOV2020. AFTER BEING
DISCHARGED ON OCT 27, 2020,
THE SUBJECT WAS
HOSPITALIZED TWO DAYS
LATER AT MERCY
BEHAVIORAL HEALTH FOR
THE SAME DIAGNOSIS.
MEDICAL RECORDS WERE
REQUESTED. UPON REVIEW OF
MEDICAL RECORDS, THE
ADMITTING DIAGNOSIS FOR
THE SUBJECT'S SECOND

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

HOSPITALIZATION WAS
"SEVERE EPISODE OF
RECURRENT MAJOR
DEPRESSIVE DISORDER." A
SEPARATE SAE WAS CREATED.

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

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:19

AEID	
Adverse event	WORSENING NICOTINE ADDICTION
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)	27 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	
416 of 2812	

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:19

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☒ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
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)	

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

AEID	USA-US111-2020-MRNA-1273-P30 1000006
Adverse event	SEVERE EPISODE OF RECURRENT MAJOR DEPRESSIVE DISORDER
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)	29 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	10 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)	29 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	10 NOV 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐

v6.020 DTW (1102) 418 of 2812

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

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 ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

THIS WAS PREVIOUSLY
SUBMITTED VIA FAX AS
"ANXIETY DISORDER." THIS IS
A 21 YEAR OLD FEMALE THAT
PRESENTED WITH A
COMPLAINT OF "PERSONAL
PLEA FOR INSANITY." SUBJECT
WAS INVOLUNTARILY
ADMITTED TO HOSPITAL ON
29OCT2020 FOR MOOD
DYSREGULATION AND
BEHAVIORAL DISTURBANCES.
THE SUBJECT'S INVOLUNTARY
ADMISSION ENDED ON 05
NOVEMBER 2020, AS THE
SUBJECT AGREED TO STAY IN
THE HOSPITAL FOR
MEDICATION ADJUSTMENT
AND STABILIZATION. THIS
SUBJECT HAS A PAST MEDICAL
HISTORY CONSISTING OF POST
TRAUMATIC STRESS
DISORDER, GENERALIZED
ANXIETY DISORDER,
DISSOCIATIVE DISORDER,
ALCOHOL ABUSE, AND
CANNABIS ABUSE. SHE WAS
RECENTLY HOSPITALIZED
26OCT2020 TO 27OCT2020 FOR
ANXIETY DISORDER.
PERTINENT LABS INCLUDE
POSITIVE FOR CANNABINOIDS
PER URINE DRUG SCREEN.
DURING THIS STAY SHE
SHOWED SIGNS OF
DISSOCIATION, DELUSION,
PARANOIA, FEELINGS OF

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

ANXIETY, FAIR SLEEP, AND
FAIR APPETITE. SHE DENIED
FEELINGS OF SUICIDE OR
HOMICIDAL IDEATION. SHE
WAS COMPLIANT WITH
MEDICATIONS THROUGHOUT
STAY. SHE ATTENDED
MULTIPLE PSYCHO-SPIRITUAL
EDUCATION GROUPS TO HELP
LEARN COPING SKILLS. SHE
WAS GIVEN A PRIMARY
DIAGNOSIS OF SEVERE
EPISODE OF RECURRENT
MAJOR DEPRESSIVE DISORDER.
ALSO GIVEN A DIAGNOSIS OF
DISSOCIATIVE DISORDER
RELATED TO PTSD. SHE WAS
DISCHARGED ON 10NOV2020
AFTER SIGNIFICANT
IMPROVEMENT AND IN STABLE
CONDITION. DISCHARGE
MEDICATIONS GIVEN INCLUDE
BUPROPION HCL ER 150MG
DAILY, CHLORPROMAZINE
100MG EVERY 4 HOURS AS
NEEDED, CLONAZEPAM 0.5MG
THREE TIMES A DAY AS
NEEDED, HYDROXYZINE HCL
50MG EVERY 6 HOURS AS
NEEDED, PRAZOSIN 2 MG
DAILY AT BEDTIME,
QUETIAPINE 300MG DAILY AT
BEDTIME, QUETIAPINE 25 MG
DAILY, AND TRAZODONE
100MG AT BEDTIME AS
NEEDED.

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

US3812059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:55:19

AEID	
Adverse event	DISSOCIATIVE DISORDER
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)	29 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	10 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	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

v6.020 DTW (1102)

422 of 2812

US3812059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:55:19

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
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) _____	

US3812059

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:55:19

AEID	USA-US111-2020-MRNA-1273-P30 1000013
Adverse event	SEVERE EPISODE OF RECURRENT MAJOR DEPRESSIVE DISORDER
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)	18 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)	
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)	18 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐

v6.020 DTW (1102) 424 of 2812

US3812059

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:55:19

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 ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☒ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3812059

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:55:19

THIS SUBJECT IS A
21-YEAR-OLD FEMALE WHO
WAS RECENTLY DISCHARGED
ON 10 NOVEMBER 2020 WITH
DIAGNOSIS OF "SEVERE
EPISODE OF RECURRENT
MAJOR DEPRESSIVE
DISORDER." PER THE SUBJECT'S
MOTHER, THE SUBJECT HAS
BEEN RECEIVING "VIRTUAL"
OUTPATIENT THERAPY 3
DAYS/WEEK SINCE LAST
FRIDAY (NOV 13, 2020). THE
OUTPATIENT CLINIC ADVISED
THE SUBJECT'S MOTHER THAT
INPATIENT THERAPY WOULD
BE MORE SUITABLE FOR THE
SUBJECT AT THIS TIME. THE
SUBJECT WAS READMITTED
FOR "SEVERE EPISODE OF
RECURRENT MAJOR
DEPRESSIVE DISORDER" ON 18
NOV 2020. NO ADDITIONAL
INFORMATION IS AVAILABLE.
MEDICAL RECORDS WILL BE
REQUESTED.

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

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:55:19

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

Yes ☒

No ☐

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

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:19

Name of Medication	NUVARING
Prophylaxis	Yes ☒ No ☐
Indication	PREGNANCY PREVENTION/ BIRTH CONTROL
Dose per administration	.135
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 ☐

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:19

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☒
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:19

Name of Medication	TRAVATAN
Prophylaxis	Yes ☐ No ☒
Indication	GLAUCOMA
Dose per administration	.05
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 ☐ Intramuscular ☐

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:19

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☒
If route of administration is Other, specify	DROP
Start date (dd MMM yyyy)	01 MAY 2018
Start date completely unknown	False
Ongoing?	Yes ☐ No ☒
If not Ongoing, End date (dd MMM yyyy)	30 OCT 2020
Was this medication taken for solicited event?	Yes ☐ No ☒
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☒

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:55:19

Name of Medication	COSOPT
Prophylaxis	Yes ☐ No ☒
Indication	GLAUCOMA
Dose per administration	.05
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 ☐ Intramuscular ☐

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:55:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☒
If route of administration is Other, specify		DROP
Start date (dd MMM yyyy)	01 MAY 2018	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:19

Name of Medication	SERTRALINE
Prophylaxis	Yes ☐ No ☒
Indication	DEPRESSION/ANXIETY
Dose per administration	100
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		20 DEC 2019
Start date completely unknown		False
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)		24 OCT 2020
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802 ☐	803 ☐
	804 ☒	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:55:19

Name of Medication	HYDROXYZINE
Prophylaxis	Yes ☐ No ☒
Indication	ANXIETY DISORDER
Dose per administration	25
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☒ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:55:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		26 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		26 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:19

Name of Medication	NICOTINE PATCH
Prophylaxis	Yes ☐ No ☒
Indication	NICOTINE ADDICTION
Dose per administration	14
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 ☐ Intramuscular ☐

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		27 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:55:19

Name of Medication	NICOTINE GUM
Prophylaxis	Yes ☐ No ☒
Indication	NICOTINE ADDICTION
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 ☐ Intraocular ☐ Intramuscular ☐

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:55:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		27 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:55:19

Name of Medication	SERTRALINE
Prophylaxis	Yes ☐ No ☒
Indication	DEPRESSION/ANXEITY
Dose per administration	150
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 ☐ Intramuscular ☐

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:55:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	24 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)	26 OCT 2020	
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	803 ☐
	804 ☒	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:55:19

Name of Medication	ALPHAGAN
Prophylaxis	Yes ☐ No ☒
Indication	GLAUCOMA
Dose per administration	0.05
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	PERCENT
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 ☒ Intramuscular ☐

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:55:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	24 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)	30 OCT 2020	
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:55:19

Name of Medication	BUPROPION XL
Prophylaxis	Yes ☐ No ☒
Indication	ANXIETY DISORDER
Dose per administration	150
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 ☐ Intramuscular ☐

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:55:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		27 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:55:19

Name of Medication	MOTRIN
Prophylaxis	Yes ☐ No ☒
Indication	SORE THROAT, MYLAGIA, HEADACHE
Dose per administration	400
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:55:19

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	08 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		13 OCT 2020
Was this medication taken for solicited event?	Yes	☒
	No	☐
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:55:19

Name of Medication	BUPROPION ER
Prophylaxis	Yes ☐ No ☒
Indication	MAJOR DEPRESSIVE DISORDER
Dose per administration	150
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 ☐ Intramuscular ☐

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:55:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		31 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:55:19

Name of Medication	CHLOPRMAZINE
Prophylaxis	Yes ☐ No ☒
Indication	MAJOR DEPRESSIVE DISORDER
Dose per administration	100
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☒
If frequency is Other, specify	
Route of administration	Q4 HOURS PRN Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:55:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		06 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:55:19

Name of Medication	CLONAZEPAM
Prophylaxis	Yes ☐ No ☒
Indication	MAJOR DEPRESSIVE DISORDER
Dose per administration	0.5
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☒
If frequency is Other, specify	
Route of administration	TID PRN Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:55:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		30 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:55:19

Name of Medication	HYDROXYZINE HCL
Prophylaxis	Yes ☐ No ☒
Indication	MAJOR DEPRESSIVE DISORDER
Dose per administration	50
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☒ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:55:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		31 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:55:19

Name of Medication	PRAZOSIN
Prophylaxis	Yes ☐ No ☒
Indication	MAJOR DEPRESSIVE DISORDER
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 ☐ Intraocular ☐ Intramuscular ☐

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:55:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		31 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:55:19

Name of Medication	QUETIAPINE
Prophylaxis	Yes ☐ No ☒
Indication	MAJOR DEPRESSIVE DISORDER
Dose per administration	300
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☒
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:55:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		31 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:55:19

Name of Medication	QUETIAPINE
Prophylaxis	Yes ☐ No ☒
Indication	MAJOR DEPRESSIVE DISORDER
Dose per administration	25
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:55:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		03 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:55:19

Name of Medication	TRAZODONE
Prophylaxis	Yes ☐ No ☒
Indication	MAJOR DEPRESSIVE DISORDER
Dose per administration	100
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:55:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		30 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:55:19

Name of Medication	LATANOPROST
Prophylaxis	Yes ☐ No ☒
Indication	GLAUCOMA
Dose per administration	0.005
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 ☒ Intramuscular ☐

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:55:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		31 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:55:19

Name of Medication	DIPHENHYDRAMINE
Prophylaxis	Yes ☐ No ☒
Indication	MAJOR DEPRESSIVE DISORDER
Dose per administration	50
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☒ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:55:19

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☒
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	30 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ☒
If not Ongoing, End date (dd MMM yyyy) 30 OCT 2020	
Was this medication taken for solicited event?	Yes ☐ No ☒
Separate Dosage Number (derived) _____	
Interval Dosage Unit Number (derived) _____	
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☐

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:55:19

Name of Medication	DORZOLAMIDE-TIMOLOL
Prophylaxis	Yes ☐ No ☒
Indication	GLAUCOMA
Dose per administration	22.3/6.8
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	MG/ML
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 ☒ Intramuscular ☐

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:55:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		01 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:55:19

Name of Medication	NICOTINE POLACRILEX LOZENGE
Prophylaxis	Yes ☐ No ☒
Indication	NICOTINE ADDICTION
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	Q2HRS PRN Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:55:19

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	31 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		8 NOV 2020
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

US3812059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:55:19

[Were any concomitant procedures performed?](#)

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3812059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 09:55:19

Procedure/Surgery date (<i>dd MMM yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify

US3812059

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:55:19

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3812059

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:55:19

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 ☐

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

SAEID	USA-US111-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	LARKIN
Investigator's Last Name	WADSWORTH
Site Address: Street	711 OLD BALLAS RD SUITE 105
Site Address: City	ST LOUIS
Site Address: State	
Site Address: Postal Code	63141
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:55:19

SAEID	USA-US111-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	LARKIN
Investigator's Last Name	WADSWORTH
Site Address: Street	711 OLD BALLAS RD SUITE 105
Site Address: City	ST LOUIS
Site Address: State	
Site Address: Postal Code	63141
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	29/OCT/2020 19:43
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

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:55:19

SAEID	USA-US111-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	LARKIN
Investigator's Last Name	WADSWORTH
Site Address: Street	711 OLD BALLAS RD SUITE 105
Site Address: City	ST LOUIS
Site Address: State	
Site Address: Postal Code	63141
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	02/NOV/2020 10:53
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

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:55:19

SAEID	USA-US111-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	LARKIN
Investigator's Last Name	WADSWORTH
Site Address: Street	711 OLD BALLAS RD SUITE 105
Site Address: City	ST LOUIS
Site Address: State	
Site Address: Postal Code	63141
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	16/NOV/2020 11:16
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

SAEID	USA-US111-2020-MRNA-1273-P301000013
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	LARKIN
Investigator's Last Name	WADSWORTH
Site Address: Street	711 OLD BALLAS RD SUITE 105
Site Address: City	ST LOUIS
Site Address: State	
Site Address: Postal Code	63141
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:55:19

SAEID	USA-US111-2020-MRNA-1273-P301000013
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	LARKIN
Investigator's Last Name	WADSWORTH
Site Address: Street	711 OLD BALLAS RD SUITE 105
Site Address: City	ST LOUIS
Site Address: State	
Site Address: Postal Code	63141
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	21/NOV/2020 10:16
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3812059 (Prod: Sundance Clinical Research - Platinum - PPDS)

US3812059

Form: Participant Creation

Generated On: 26 Nov 2020 09:55:19

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3812059'	RWS_ENDPOINT ENDPOINT (b) (4) 	06 Aug 2020 15:29:57

US3812059

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:55:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	06 Aug 2020 16:12:38

US3812059

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '06 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	06 Aug 2020 15:29:58

US3812059

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Heather Cherniawski (b) (4)	06 Aug 2020 16:12:38

US3812059

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:55:19

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	06 Aug 2020 16:12:38

US3812059

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:19

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1999'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	06 Aug 2020 15:29:59

US3812059

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:19

[Age](#)

Audit	User	Time (GMT)
User entered '20'	Heather Cherniawski (b) (4)	06 Aug 2020 16:13:23

US3812059

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:19

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	06 Aug 2020 16:13:23

US3812059

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:19

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '20'	System	06 Aug 2020 16:13:45

US3812059

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:19

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	Heather Cherniawski (b) (4)	06 Aug 2020 16:13:23

US3812059

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:19

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Heather Cherniawski (b) (4)	06 Aug 2020 16:13:23

US3812059

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:19

[White](#)

Audit	User	Time (GMT)
User entered '1'	Heather Cherniawski (b) (4)	06 Aug 2020 16:13:23

US3812059

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:19

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	06 Aug 2020 16:13:23

US3812059

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:19

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	06 Aug 2020 16:13:23

US3812059

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:19

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	06 Aug 2020 16:13:23

US3812059

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:19

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	06 Aug 2020 16:13:23

US3812059

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:19

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	06 Aug 2020 16:13:23

US3812059

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:19

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	06 Aug 2020 16:13:23

US3812059

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:19

Unknown

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	06 Aug 2020 16:13:23

US3812059

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:19

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	06 Aug 2020 16:13:23

US3812059

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '06 Aug 2020' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	10 Nov 2020 17:35:49
User entered '6 Aug 2020'	Heather Cherniawski (b) (4)	06 Aug 2020 16:13:45

US3812059

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	06 Aug 2020 16:13:45

US3812059

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '2020'	System	06 Aug 2020 16:13:45

US3812059

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:55:19

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 1 (1)'	Heather Cherniawski (b) (4)	06 Aug 2020 16:13:45

US3812059

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	06 Aug 2020 16:13:45

US3812059

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	06 Aug 2020 16:13:45

US3812059

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:55:19

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	06 Aug 2020 16:13:45

US3812059

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:55:19

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Cherniawski (b) (4)	06 Aug 2020 16:13:45

US3812059

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:55:19

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	06 Aug 2020 15:29:58

US3812059

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:55:19

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 16:13:54

US3812059

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	06 Aug 2020 16:13:54

US3812059

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:55:19

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:45:53

US3812059

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:55:19

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify the laterality of GLAUCOMA (e.g. Left, Right or Bilateral Glaucoma). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 17:24:06
User coded data point as SOC: Eye disorders, HLGT: Glaucoma and ocular hypertension, HLT: Glaucomas (excl congenital), PT: Glaucoma, LLT: Glaucoma - version MedDRA\23.0.	Coder Import (b) (4)	26 Oct 2020 19:47:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	26 Oct 2020 19:47:23
Data point term sent to Coder	System	26 Oct 2020 19:36:37
Query 'Per DM CLR: Please specify the laterality of GLAUCOMA (e.g. Left, Right or Bilateral Glaucoma). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'UPDATED' (Site from DM).	Heather Cherniawski	26 Oct 2020 19:36:15
Coding entries removed.	(b) (4)	26 Oct 2020 19:36:06
User entered 'LEFT EYE GLAUCOMA' reason for change: Data Entry Error	Heather Cherniawski	26 Oct 2020 19:36:06
User opened query 'Per DM CLR: Please specify the laterality of GLAUCOMA (e.g. Left, Right or Bilateral Glaucoma). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 04:21:11
User coded data point as SOC: Eye disorders, HLGT: Glaucoma and ocular hypertension, HLT: Glaucomas (excl congenital), PT: Glaucoma, LLT: Glaucoma - version MedDRA\23.0.	Coder Import (b) (4)	07 Aug 2020 13:48:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	07 Aug 2020 13:48:14
Data point term sent to Coder	System	07 Aug 2020 13:46:58
User entered 'GLAUCOMA'	Heather Cherniawski	07 Aug 2020 13:46:25
	(b) (4)	

US3812059

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered (b) (6) 1999'	Heather Cherniawski (b) (4)	07 Aug 2020 13:46:25

US3812059

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:55:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	07 Aug 2020 13:46:25

US3812059

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:55:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:46:25

US3812059

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 13:46:25

US3812059

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:55:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	07 Aug 2020 13:46:25

US3812059

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered (b) (6) 1999'	System	07 Aug 2020 13:46:25

US3812059

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '1999'	System	07 Aug 2020 13:46:25

US3812059

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 13:46:25

US3812059

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 13:46:25

US3812059

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:55:19

[Condition](#)

Audit	User	Time (GMT)
Query 'Hospital records indicate Dissociative disorder and Borderline Personality Disorder. Please review and reconcile.' answered with 'Per PI, "AE's, Not SAE- Documentation of these conditions lacking prior to hospital stay with psychiatry consult" ' (Site from CRA).	Lyly Dang (b) (4)	24 Nov 2020 20:08:57
Query 'Condition is listed as "Depression" but con meds give the indication as "Major Depressive Disorder" Please reconcile.' answered with 'Con Meds were given for the corresponding SAE. Reviewed with PI and PI agrees' (Site from CRA).	Lyly Dang (b) (4)	24 Nov 2020 20:08:13
User opened query 'Hospital records indicate Dissociative disorder and Borderline Personality Disorder. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 20:23:42
Query 'Subject records indicate a pre-existing diagnosis of PTSD, yet this is absent from the medical history. Please clarify.' canceled (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 20:22:40
User opened query 'Subject records indicate a pre-existing diagnosis of PTSD, yet this is absent from the medical history. Please clarify.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 18:49:39
User opened query 'Condition is listed as "Depression" but con meds give the indication as "Major Depressive Disorder" Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 18:31:04
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\23.0.	Coder Import (b) (4)	07 Aug 2020 13:48:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	07 Aug 2020 13:48:14
Data point term sent to Coder	System	07 Aug 2020 13:46:58
User entered 'DEPRESSION'	Heather Cherniawski	07 Aug 2020 13:46:41
	(b) (4)	

US3812059

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'UN UNK 2018'	Heather Cherniawski (b) (4)	07 Aug 2020 13:46:41

US3812059

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:55:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	07 Aug 2020 13:46:41

US3812059

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:55:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:46:41

US3812059

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 13:46:41

US3812059

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:55:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	07 Aug 2020 13:46:41

US3812059

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	07 Aug 2020 13:46:41

US3812059

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '2018'	System	07 Aug 2020 13:46:41

US3812059

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 13:46:41

US3812059

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 13:46:41

US3812059

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:55:19

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 20:32:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 20:32:18
Data point term sent to Coder	System	07 Aug 2020 13:48:01
User entered 'ATROPINE ALLERGY'	Heather Cherniawski (b) (4)	07 Aug 2020 13:47:14

US3812059

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User closed query 'Start date is prior to Date of Birth. System Please correct.' (Site from System).		08 Aug 2020 16:23:10
User entered '(b) (6) 1999' reason for change: New Information	Anya Penly (b) (4)	08 Aug 2020 16:23:10
User opened query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	(b) (4)	07 Aug 2020 13:47:14
User entered 'UN UNK 1999'	Heather Cherniawski (b) (4)	07 Aug 2020 13:47:14

US3812059

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:55:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	07 Aug 2020 13:47:14

US3812059

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:55:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:47:14

US3812059

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 13:47:14

US3812059

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:55:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	07 Aug 2020 13:47:14

US3812059

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered (b) (6) 1999'	System	08 Aug 2020 16:23:10
User entered 'Jan 1999'	System	07 Aug 2020 13:47:14

US3812059

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '1999'	System	07 Aug 2020 13:47:14

US3812059

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 13:47:14

US3812059

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 13:47:14

US3812059

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:55:19

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Frequent headaches - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 13:49:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 13:49:10
Data point term sent to Coder	System	07 Aug 2020 13:47:59
User entered 'FREQUENT HEADACHES'	Heather Cherniawski (b) (4)	07 Aug 2020 13:47:37

US3812059

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'UN UNK 2008'	Heather Cherniawski (b) (4)	07 Aug 2020 13:47:37

US3812059

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:55:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	07 Aug 2020 13:47:37

US3812059

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:55:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:47:37

US3812059

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 13:47:37

US3812059

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:55:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	07 Aug 2020 13:47:37

US3812059

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'Jan 2008'	System	07 Aug 2020 13:47:37

US3812059

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '2008'	System	07 Aug 2020 13:47:37

US3812059

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 13:47:37

US3812059

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 13:47:37

US3812059

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:55:19

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Tobacco use, PT: Electronic cigarette user, LLT: Vapor cigarette smoker - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 10:48:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 10:48:19
Data point term sent to Coder	System	07 Aug 2020 13:47:59
User entered 'VAPE SMOKER'	Heather Cherniawski (b) (4)	07 Aug 2020 13:47:58

US3812059

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'UN UNK 2018'	Heather Cherniawski (b) (4)	07 Aug 2020 13:47:58

US3812059

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:55:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	07 Aug 2020 13:47:58

US3812059

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:55:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:47:58

US3812059

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 13:47:58

US3812059

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:55:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	07 Aug 2020 13:47:58

US3812059

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	07 Aug 2020 13:47:58

US3812059

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '2018'	System	07 Aug 2020 13:47:58

US3812059

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 13:47:58

US3812059

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 13:47:58

US3812059

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:55:19

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: Eye therapeutic procedures, HLT: Eye therapeutic procedures NEC, PT: Eye operation, LLT: Eye operation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 04:35:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 04:35:48
Data point term sent to Coder	System	07 Aug 2020 13:50:02
User entered 'LEFT EYE SHUNT REVISION X18'	Heather Cherniawski (b) (4)	07 Aug 2020 13:49:07

US3812059

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User closed query 'Start date is prior to Date of Birth. System Please correct.' (Site from System).		08 Aug 2020 16:23:28
User entered (b) (6) 1999' reason for change: Data Entry Error	Anya Penly (b) (4)	08 Aug 2020 16:23:28
User opened query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	(b) (4)	07 Aug 2020 13:49:07
User entered 'UN UNK 1999'	Heather Cherniawski (b) (4)	07 Aug 2020 13:49:07

US3812059

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:55:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	07 Aug 2020 13:49:07

US3812059

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:55:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:49:07

US3812059

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'UN UNK 2013'	Heather Cherniawski (b) (4)	07 Aug 2020 13:49:07

US3812059

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:55:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	07 Aug 2020 13:49:07

US3812059

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered (b) (6) 1999'	System	08 Aug 2020 16:23:28
User entered 'Jan 1999'	System	07 Aug 2020 13:49:07

US3812059

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '1999'	System	07 Aug 2020 13:49:07

US3812059

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'Jan 2013'	System	07 Aug 2020 13:49:07

US3812059

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '2013'	System	07 Aug 2020 13:49:07

US3812059

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:55:19

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Lid, lash and lacrimal structural disorders, PT: Eyelid retraction, LLT: Eyelid retraction - version MedDRA\23.0.	Coder Import (b) (4)	02 Nov 2020 08:59:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	02 Nov 2020 08:59:52
Data point term sent to Coder	System	01 Nov 2020 01:08:43
Coding entries removed.	Lyly Dang (b) (4)	01 Nov 2020 01:08:04
User entered '(B) EYELID RETRACTION' reason for change: Data Entry Error	Lyly Dang (b) (4)	01 Nov 2020 01:08:04
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Lid, lash and lacrimal structural disorders, PT: Eyelid retraction, LLT: Eyelid retraction - version MedDRA\23.0.	Coder Import (b) (4)	12 Aug 2020 11:38:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	12 Aug 2020 11:38:22
Data point term sent to Coder	System	11 Aug 2020 22:30:53
User entered '(R) EYELID RETRACTION'	Breanna Galibert (b) (4)	11 Aug 2020 22:30:25
	(b) (4)	

US3812059

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 22:30:25

US3812059

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:55:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 22:30:25

US3812059

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:55:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 22:30:25

US3812059

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 22:30:25

US3812059

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:55:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 22:30:25

US3812059

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 22:30:25

US3812059

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 22:30:25

US3812059

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 22:30:25

US3812059

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 22:30:25

US3812059

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:55:19

[Condition](#)

Audit	User	Time (GMT)
Query 'Hospital records indicate GAD. Please reconcile.' answered with 'Reviewed with PI. Term "Anxiety" will be kept as past medical history. Thank you' (Site from CRA).	Lyly Dang (b) (4)	24 Nov 2020 20:11:15
User opened query 'Hospital records indicate GAD. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 20:24:38
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:24:41
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 19:47:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	26 Oct 2020 19:47:52
Data point term sent to Coder	System	26 Oct 2020 19:42:52
User entered 'ANXIETY'	Heather Cherniawski	26 Oct 2020 19:42:48
	(b) (4)	

US3812059

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:24:43
User entered 'UN UNK 2018'	Heather Cherniawski (b) (4)	26 Oct 2020 19:42:48

US3812059

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:55:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:24:44
User entered '0'	Heather Cherniawski (b) (4)	26 Oct 2020 19:42:48

US3812059

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:55:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:24:46
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	26 Oct 2020 19:42:48

US3812059

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:24:48
User entered empty.	Heather Cherniawski (b) (4)	26 Oct 2020 19:42:48

US3812059

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:55:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	26 Oct 2020 19:42:48

US3812059

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	26 Oct 2020 19:42:48

US3812059

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '2018'	System	26 Oct 2020 19:42:48

US3812059

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 19:42:48

US3812059

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 19:42:48

US3812059

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:55:19

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:24:22
User coded data point as SOC: Psychiatric disorders, HLT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Nicotine dependence, LLT: Nicotine addiction - version MedDRA\\23.0.	Coder Import (b) (4)	01 Nov 2020 01:15:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	01 Nov 2020 01:15:43
Data point term sent to Coder	System	01 Nov 2020 01:14:44
User entered 'Nicotine addiction'	Lyly Dang (b) (4)	01 Nov 2020 01:14:40

US3812059

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:24:24
User entered 'un Jan 2020'	Lyly Dang (b) (4)	01 Nov 2020 01:14:40

US3812059

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:55:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:24:26
User entered '0'	Lyly Dang (b) (4)	01 Nov 2020 01:14:40

US3812059

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:55:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:24:27
User entered 'Yes (Y)'	Lyly Dang (b) (4)	01 Nov 2020 01:14:40

US3812059

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:24:29
User entered empty.	Lyly Dang (b) (4)	01 Nov 2020 01:14:40

US3812059

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:55:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:24:31
User entered '0'	Lyly Dang (b) (4)	01 Nov 2020 01:14:40

US3812059

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'Jan 2020'	System	01 Nov 2020 01:14:40

US3812059

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '2020'	System	01 Nov 2020 01:14:40

US3812059

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	System	01 Nov 2020 01:14:40

US3812059

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	System	01 Nov 2020 01:14:40

US3812059

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:55:19

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:24:06
User coded data point as SOC: Psychiatric disorders, HLT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Drug abuse, LLT: Marijuana abuse - version MedDRA\23.0.	Coder Import (b) (4)	03 Nov 2020 17:06:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	
Data point term sent to Coder	Coder Import (b) (4)	03 Nov 2020 17:06:21
User entered 'MARIJUANA ABUSE'	System	03 Nov 2020 17:05:26
	Angie Kean (b) (4)	03 Nov 2020 17:04:58
	(b) (4)	

US3812059

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:24:08
User entered 'UN Feb 2019'	Angie Kean (b) (4) (b) (4)	03 Nov 2020 17:04:58

US3812059

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:55:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:24:09
User entered '0'	Angie Kean (b) (4) (b) (4)	03 Nov 2020 17:04:58

US3812059

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:55:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:24:12
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	03 Nov 2020 17:04:58

US3812059

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:24:13
User entered empty.	Angie Kean (b) (4) (b) (4)	03 Nov 2020 17:04:58

US3812059

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:55:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:24:15
User entered '0'	Angie Kean (b) (4) (b) (4)	03 Nov 2020 17:04:58

US3812059

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'Feb 2019'	System	03 Nov 2020 17:04:58

US3812059

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '2019'	System	03 Nov 2020 17:04:58

US3812059

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:04:58

US3812059

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:04:58

US3812059

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:55:19

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Stress disorders, PT: Post-traumatic stress disorder, LLT: Post-traumatic stress disorder - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 18:55:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 18:55:51
Data point term sent to Coder	System	16 Nov 2020 18:55:34
User entered 'post traumatic stress disorder'	Breanna Galibert (b) (4)	16 Nov 2020 18:55:28

US3812059

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'un Jan 2020'	Breanna Galibert (b) (4) (b) (4)	16 Nov 2020 18:55:28

US3812059

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:55:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	16 Nov 2020 18:55:28

US3812059

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:55:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	16 Nov 2020 18:55:28

US3812059

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	16 Nov 2020 18:55:28

US3812059

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:55:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	16 Nov 2020 18:55:28

US3812059

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'Jan 2020'	System	16 Nov 2020 18:55:28

US3812059

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '2020'	System	16 Nov 2020 18:55:28

US3812059

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 18:55:28

US3812059

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 18:55:28

US3812059

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:55:19

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Alcohol use disorder, LLT: Alcohol use disorder - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 18:57:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 18:57:48
Data point term sent to Coder	System	16 Nov 2020 18:56:36
User entered 'alcohol use disorder'	Breanna Galibert (b) (4)	16 Nov 2020 18:55:52

US3812059

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'un Jan 2020'	Breanna Galibert (b) (4) (b) (4)	16 Nov 2020 18:55:52

US3812059

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:55:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	16 Nov 2020 18:55:52

US3812059

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:55:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	16 Nov 2020 18:55:52

US3812059

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	16 Nov 2020 18:55:52

US3812059

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:55:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	16 Nov 2020 18:55:52

US3812059

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'Jan 2020'	System	16 Nov 2020 18:55:52

US3812059

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '2020'	System	16 Nov 2020 18:55:52

US3812059

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 18:55:52

US3812059

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 18:55:52

US3812059

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:49:43

US3812059

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '06 Aug 2020' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	10 Nov 2020 17:36:34
User entered '6 Aug 2020'	Heather Cherniawski (b) (4)	07 Aug 2020 13:49:43

US3812059

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '09:30'	Heather Cherniawski (b) (4)	07 Aug 2020 13:49:43

US3812059

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '06 Aug 2020 09:30'	System	10 Nov 2020 17:36:34
User entered '6 Aug 2020 09:30'	System	07 Aug 2020 13:49:43

US3812059

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '64.8' in	Heather Cherniawski	07 Aug 2020 13:49:43
DataPoint set to visible.	(b) (4) System	06 Aug 2020 16:13:54

US3812059

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '137' lb	Heather Cherniawski	07 Aug 2020 13:49:43
DataPoint set to visible.	(b) (4) System	06 Aug 2020 16:13:54

US3812059

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '22.98690'	System	16 Sep 2020 23:45:29
User entered '23.0'	System	07 Aug 2020 13:49:43
DataPoint set to visible.	System	06 Aug 2020 16:13:54

US3812059

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	07 Aug 2020 13:49:43
DataPoint set to visible.	System	06 Aug 2020 16:13:54

US3812059

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Per CDM: For combined visit, to be marked as 'ND'. ' (Site from DM).	(b) (4), (b) (6)	26 Aug 2020 05:51:40
Query 'Per CDM: For combined visit, to be marked as 'ND'. ' answered with 'corrected per query' (Site from DM).	Anya Penly (b) (4)	25 Aug 2020 15:33:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Aug 2020 15:33:20
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 16:57:39
User opened query 'Per CDM: For combined visit, to be marked as 'ND'. ' (Site from DM).	(b) (4), (b) (6)	11 Aug 2020 16:57:37
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Heather Cherniawski (b) (4)	07 Aug 2020 13:49:50
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Aug 2020 13:49:43
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 13:49:43

US3812059

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

[Route of measurement](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Site response noted Route of measurement is updated only when Temperature is recorded. Hence the temperature is ND-Not done please consider keeping Route of measurement field blank. ' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 06:21:58
Query 'Per CDM: Site response noted Route of measurement is updated only when Temperature is recorded. Hence the temperature is ND-Not done please consider keeping Route of measurement field blank. ' answered with 'corrected per query' (Site from DM).	Anya Penly (b) (4) (b) (4)	26 Aug 2020 14:35:21
User entered empty; reason for change Data Entry Error	Anya Penly (b) (4) (b) (4)	26 Aug 2020 14:35:11
User opened query 'Per CDM: Site response noted Route of measurement is updated only when Temperature is recorded. Hence the temperature is ND-Not done please consider keeping Route of measurement field blank. ' (Site from DM).	(b) (4), (b) (6)	26 Aug 2020 05:58:58
User closed query 'Per CDM: For combined visit, to be marked as 'ND'. ' (Site from DM).	(b) (4), (b) (6)	26 Aug 2020 05:51:49
Query 'Per CDM: For combined visit, to be marked as 'ND'. ' answered with 'corrected per query' (Site from DM).	Anya Penly (b) (4) (b) (4)	25 Aug 2020 15:33:39
User entered 'Other (Other)' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	25 Aug 2020 15:33:20
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 16:57:44
User opened query 'Per CDM: For combined visit, to be marked as 'ND'. ' (Site from DM).	(b) (4), (b) (6)	11 Aug 2020 16:57:43
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Heather Cherniawski (b) (4)	07 Aug 2020 13:49:55
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Aug 2020 13:49:43
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 13:49:43

US3812059

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Anya Penly (b) (4)	26 Aug 2020 14:35:11
User entered missing code ND - Not Done; reason for change Data Entry Error	Anya Penly (b) (4)	25 Aug 2020 15:33:20
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 13:49:43

US3812059

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: For combined visit, to be marked as 'ND'. ' (Site from DM).	(b) (4), (b) (6)	26 Aug 2020 07:32:27
Query 'Per CDM: For combined visit, to be marked as 'ND'. ' answered with 'corrected per query' (Site from DM).	Anya Penly (b) (4)	25 Aug 2020 15:33:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Aug 2020 15:33:20
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 16:57:50
User opened query 'Per CDM: For combined visit, to be marked as 'ND'. ' (Site from DM).	(b) (4), (b) (6)	11 Aug 2020 16:57:49
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Heather Cherniawski (b) (4)	07 Aug 2020 13:49:59
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Aug 2020 13:49:43
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 13:49:43

US3812059

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	25 Aug 2020 15:33:20
User entered empty.	System	07 Aug 2020 13:49:43

US3812059

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User closed query 'Per CDM: For combined visit, to be marked as 'ND'. ' (Site from DM).	(b) (4), (b) (6)	26 Aug 2020 07:32:29
Query 'Per CDM: For combined visit, to be marked as 'ND'. ' answered with 'corrected per query' (Site from DM).	Anya Penly (b) (4) (b) (4)	25 Aug 2020 15:33:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Anya Penly (b) (4) (b) (4)	25 Aug 2020 15:33:20
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 16:57:56
User opened query 'Per CDM: For combined visit, to be marked as 'ND'. ' (Site from DM).	(b) (4), (b) (6)	11 Aug 2020 16:57:54
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Heather Cherniawski (b) (4)	07 Aug 2020 13:50:03
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Aug 2020 13:49:43
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 13:49:43

US3812059

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	25 Aug 2020 15:33:20
User entered empty.	System	07 Aug 2020 13:49:43

US3812059

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Per CDM: For combined visit, to be marked as 'ND'. ' (Site from DM).	(b) (4), (b) (6)	26 Aug 2020 07:32:30
Query 'Per CDM: For combined visit, to be marked as 'ND'. ' answered with 'corrected per query' (Site from DM).	Anya Penly (b) (4)	25 Aug 2020 15:33:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Aug 2020 15:33:20
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 16:58:01
User opened query 'Per CDM: For combined visit, to be marked as 'ND'. ' (Site from DM).	(b) (4), (b) (6)	11 Aug 2020 16:57:59
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Heather Cherniawski (b) (4)	07 Aug 2020 13:50:07
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Aug 2020 13:49:43
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 13:49:43

US3812059

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Aug 2020 15:33:20
User entered empty.	System	07 Aug 2020 13:49:43

US3812059

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Per CDM: For combined visit, to be marked as 'ND'. ' (Site from DM).	(b) (4), (b) (6)	26 Aug 2020 07:32:32
Query 'Per CDM: For combined visit, to be marked as 'ND'. ' answered with 'corrected per query' (Site from DM).	Anya Penly (b) (4)	25 Aug 2020 15:33:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Aug 2020 15:33:20
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 16:58:05
User opened query 'Per CDM: For combined visit, to be marked as 'ND'. ' (Site from DM).	(b) (4), (b) (6)	11 Aug 2020 16:58:04
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Heather Cherniawski (b) (4)	07 Aug 2020 13:50:09
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Aug 2020 13:49:43
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 13:49:43

US3812059

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Aug 2020 15:33:20
User entered empty.	System	07 Aug 2020 13:49:43

US3812059

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:55:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:50:43

US3812059

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:55:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '06 Aug 2020' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	10 Nov 2020 17:36:42
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	07 Sep 2020 10:59:13
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	01 Sep 2020 20:40:06
User entered '6 Aug 2020'	Heather Cherniawski (b) (4)	07 Aug 2020 13:50:43

US3812059

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:55:19

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '06 Aug 2020' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	10 Nov 2020 17:37:10
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 13:51:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Aug 2020 13:51:25
User entered '6 Aug 2020' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	07 Aug 2020 13:51:25
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 13:51:15
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 13:51:15

US3812059

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:51:15

US3812059

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 13:51:15

US3812059

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 13:51:15

US3812059

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 13:51:15

US3812059

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:55:19

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	07 Aug 2020 13:51:15

US3812059

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 13:51:15

US3812059

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:55:19

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	07 Aug 2020 13:51:15

US3812059

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:19

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:52:57

US3812059

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:19

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '06 Aug 2020' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	10 Nov 2020 17:37:23
User entered '6 Aug 2020'	Heather Cherniawski (b) (4)	07 Aug 2020 13:52:57

US3812059

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:19

[Test performed](#)

Audit	User	Time (GMT)
User entered 'Urine (URINE)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:52:57

US3812059

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:19

[Result](#)

Audit	User	Time (GMT)
User entered 'Negative (NEGATIVE)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:52:57

US3812059

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:19

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:52:57

US3812059

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:19

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 13:52:57

US3812059

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:19

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 13:52:57

US3812059

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 13:52:57

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:53:38

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:53:38

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:53:38

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:53:38

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:53:38

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:53:38

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:53:38

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:53:38

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:53:38

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:53:38

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:53:38

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:19

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:53:38

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:19

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 13:53:38

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:19

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	07 Aug 2020 13:53:38

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	07 Aug 2020 13:53:38

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	07 Aug 2020 13:53:38

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '1'	Heather Cherniawski (b) (4)	07 Aug 2020 13:53:38

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	07 Aug 2020 13:53:38

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	07 Aug 2020 13:53:38

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:19

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	07 Aug 2020 13:53:38

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:19

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 13:53:38

US3812059

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:55:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:54:11

US3812059

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '06 Aug 2020' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	10 Nov 2020 17:37:37
User entered '6 Aug 2020'	Heather Cherniawski (b) (4)	07 Aug 2020 13:54:11

US3812059

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:54:11

US3812059

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:55:19

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	07 Aug 2020 13:54:11

US3812059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '06 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	06 Aug 2020 15:40:02

US3812059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:55:19

What was the participant's randomization number?

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:31:20
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:31:20
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Aug 2020 15:40:02
User entered '101557' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	06 Aug 2020 15:40:02

US3812059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	06 Aug 2020 15:40:02

US3812059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:56:32

US3812059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:56:32

US3812059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:55:19

Severe obesity (body mass index $\geq$ 40kg/m²)

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:56:32

US3812059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:55:19

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:56:32

US3812059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:55:19

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:56:32

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:55:19

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Heather Cherniawski (b) (4)	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:55:19

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Heather Cherniawski (b) (4)	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:55:19

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Heather Cherniawski (b) (4)	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:55:19

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Heather Cherniawski (b) (4)	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:19

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '06 Aug 2020' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	10 Nov 2020 17:38:04
User entered '6 Aug 2020'	Heather Cherniawski (b) (4)	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '09:30'	Heather Cherniawski (b) (4)	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '06 Aug 2020 09:30'	System	10 Nov 2020 17:38:04
User entered '6 Aug 2020 09:30'	System	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.2' F	Heather Cherniawski (b) (4)	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:19

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:19

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '76'	Heather Cherniawski (b) (4)	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '15'	Heather Cherniawski (b) (4)	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '101'	Heather Cherniawski (b) (4)	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '62'	Heather Cherniawski (b) (4)	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:55:19

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Heather Cherniawski (b) (4)	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:55:19

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Heather Cherniawski (b) (4)	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:19

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '06 Aug 2020' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	10 Nov 2020 17:38:04
User entered '6 Aug 2020'	Heather Cherniawski (b) (4)	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 16:45:45
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'DM error' (Site from System).	Anya Penly (b) (4)	08 Aug 2020 13:56:09
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		07 Aug 2020 13:59:11
User entered '11:30'	Heather Cherniawski (b) (4)	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:30'	System	10 Nov 2020 17:38:04
User entered '6 Aug 2020 11:30'	System	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.2' F	Heather Cherniawski (b) (4)	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:19

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:19

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '70'	Heather Cherniawski (b) (4)	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '16'	Heather Cherniawski (b) (4)	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '110'	Heather Cherniawski (b) (4)	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '60'	Heather Cherniawski (b) (4)	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:55:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Karen Knapp (b) (4)	16 Sep 2020 23:03:57
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	07 Aug 2020 14:11:33

US3812059

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:55:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Karen Knapp (b) (4)	16 Sep 2020 23:03:57
User entered '6 Aug 2020'	Heather Cherniawski (b) (4)	07 Aug 2020 14:11:33

US3812059

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:19

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: If Screening visit and Dosing are done on the same day, then Pregnancy test should only be completed at the 'Screening Visit' only and marked as "No" at V1D1 to avoid duplication. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 10:30:43
Query 'Per CDM: If Screening visit and Dosing are done on the same day, then Pregnancy test should only be completed at the 'Screening Visit' only and marked as "No" at V1D1 to avoid duplication. Please review and update accordingly.' answered with 'UPDATED PER QUERY ' (Site from DM).	Breanna Galibert (b) (4)	06 Oct 2020 20:53:11
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	06 Oct 2020 20:53:06
User opened query 'Per CDM: If Screening visit and Dosing are done on the same day, then Pregnancy test should only be completed at the 'Screening Visit' only and marked as "No" at V1D1 to avoid duplication. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 09:39:01
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	07 Aug 2020 14:11:59

US3812059

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:19

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	06 Oct 2020 20:53:06
User entered '6 Aug 2020'	Heather Cherniawski (b) (4)	07 Aug 2020 14:11:59

US3812059

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:19

[Test performed](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	06 Oct 2020 20:53:06
User entered 'Urine (URINE)'	Heather Cherniawski (b) (4)	07 Aug 2020 14:11:59

US3812059

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:19

[Result](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	06 Oct 2020 20:53:06
User entered 'Negative (NEGATIVE)'	Heather Cherniawski (b) (4)	07 Aug 2020 14:11:59

US3812059

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:19

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	06 Oct 2020 20:53:06
User entered 'No (N)'	Heather Cherniawski (b) (4)	07 Aug 2020 14:11:59

US3812059

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:19

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 14:11:59

US3812059

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:19

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 14:11:59

US3812059

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 14:11:59

US3812059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:55:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	06 Aug 2020 16:35:18

US3812059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:55:19

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	06 Aug 2020 16:35:18

US3812059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	06 Aug 2020 16:35:18

US3812059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:55:19

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	06 Aug 2020 16:35:18

US3812059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:55:19

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	10 Nov 2020 17:38:21
User entered '6 Aug 2020'	Heather Cherniawski (b) (4)	06 Aug 2020 16:35:18

US3812059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '10:57'	Heather Cherniawski (b) (4)	06 Aug 2020 16:35:18

US3812059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '06 Aug 2020 10:57'	System	10 Nov 2020 17:38:21
User entered '6 Aug 2020 10:57'	System	06 Aug 2020 16:35:18

US3812059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Heather Cherniawski (b) (4)	06 Aug 2020 16:35:18

US3812059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	06 Aug 2020 16:35:18

US3812059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:55:19

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	06 Aug 2020 16:35:18

US3812059

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:59:51

US3812059

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:19

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '06 Aug 2020' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	10 Nov 2020 17:38:28
User entered '6 Aug 2020'	Heather Cherniawski (b) (4)	07 Aug 2020 13:59:51

US3812059

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '10:35'	Heather Cherniawski (b) (4)	07 Aug 2020 13:59:51

US3812059

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '06 Aug 2020 10:35'	System	10 Nov 2020 17:38:28
User entered '6 Aug 2020 10:35'	System	07 Aug 2020 13:59:51

US3812059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:55:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '06 Aug 2020' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	10 Nov 2020 17:38:36
User entered '6 Aug 2020'	Heather Cherniawski (b) (4)	07 Aug 2020 14:00:09

US3812059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:55:19

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Heather Cherniawski (b) (4)	07 Aug 2020 14:00:09

US3812059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:55:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	07 Aug 2020 14:00:09

US3812059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:55:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '10:38'	Heather Cherniawski (b) (4)	07 Aug 2020 14:00:09

US3812059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '06 Aug 2020 10:38'	System	10 Nov 2020 17:38:36
User entered '6 Aug 2020 10:38'	System	07 Aug 2020 14:00:09

US3812059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:55:19

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Heather Cherniawski (b) (4)	07 Aug 2020 14:00:09

US3812059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:55:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 14:00:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Aug 2020 14:00:13
User entered 'No (N)' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	07 Aug 2020 14:00:13
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 14:00:09
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 14:00:09

US3812059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:55:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 14:00:09

US3812059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 14:00:09

US3812059

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	13 Aug 2020 20:09:42

US3812059

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:55:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 20:09:42

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 16:35:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-06T11:36:12', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '04d995e3-bfbe-4e1d-88d3-14bf9fce090e'	System	06 Aug 2020 16:36:29
User entered 'Yes (Y)'	System	06 Aug 2020 16:36:29

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-06T11:36:19', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '04d995e3-bfbe-4e1d-88d3-14bf9fce090e'	System	06 Aug 2020 16:36:29
User entered '98.2'	System	06 Aug 2020 16:36:29

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-06T11:36:23', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '04d995e3-bfbe-4e1d-88d3-14bf9fce090e'	System	06 Aug 2020 16:36:29
User entered 'No (N)'	System	06 Aug 2020 16:36:29

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-06T11:36:27', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '04d995e3-bfbe-4e1d-88d3-14bf9fce090e'	System	06 Aug 2020 16:36:29
User entered '06 Aug 2020 11:36'	System	06 Aug 2020 16:36:29

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:17'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 13:47'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 16:35:18
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-06T23:13:59', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '5b503f5f-d618-4cbd-8c49-6681de596b2f'	System	07 Aug 2020 04:15:50
User entered 'Yes (Y)'	System	07 Aug 2020 04:15:50

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-06T23:15:36', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '5b503f5f-d618-4cbd-8c49-6681de596b2f'	System	07 Aug 2020 04:15:50
User entered '99.3'	System	07 Aug 2020 04:15:50

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-06T23:15:41', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '5b503f5f-d618-4cbd-8c49-6681de596b2f'	System	07 Aug 2020 04:15:50
User entered 'No (N)'	System	07 Aug 2020 04:15:50

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-06T23:15:45', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '5b503f5f-d618-4cbd-8c49-6681de596b2f'	System	07 Aug 2020 04:15:50
User entered '06 Aug 2020 23:15'	System	07 Aug 2020 04:15:50

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 14:42'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 16:35:18
User entered 'Day 2'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:55:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-07T22:32:32', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '6394aa80-7ae3-43ab-b490-6a42d99a6c10'	System	08 Aug 2020 03:32:50
User entered 'Yes (Y)'	System	08 Aug 2020 03:32:50

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:55:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-07T22:32:39', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '6394aa80-7ae3-43ab-b490-6a42d99a6c10'	System	08 Aug 2020 03:32:50
User entered '98.7'	System	08 Aug 2020 03:32:50

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-07T22:32:46', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '6394aa80-7ae3-43ab-b490-6a42d99a6c10'	System	08 Aug 2020 03:32:50
User entered 'No (N)'	System	08 Aug 2020 03:32:50

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:55:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-07T22:32:48', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '6394aa80-7ae3-43ab-b490-6a42d99a6c10'	System	08 Aug 2020 03:32:50
User entered '07 Aug 2020 22:32'	System	08 Aug 2020 03:32:50

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 16:35:18
User entered 'Day 3'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:55:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-08T22:25:48', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '0a89eba1-f421-48d3-ba90-5237c6cb0cd7'	System	09 Aug 2020 03:26:01
User entered 'Yes (Y)'	System	09 Aug 2020 03:26:01

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:55:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-08T22:25:51', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '0a89eba1-f421-48d3-ba90-5237c6cb0cd7'	System	09 Aug 2020 03:26:01
User entered '99.0'	System	09 Aug 2020 03:26:01

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-08T22:25:54', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '0a89eba1-f421-48d3-ba90-5237c6cb0cd7'	System	09 Aug 2020 03:26:01
User entered 'No (N)'	System	09 Aug 2020 03:26:01

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:55:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-08T22:25:56', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '0a89eba1-f421-48d3-ba90-5237c6cb0cd7'	System	09 Aug 2020 03:26:01
User entered '08 Aug 2020 22:25'	System	09 Aug 2020 03:26:01

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 16:35:18
User entered 'Day 4'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:55:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-09T18:19:07', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '1f8f3e39-e1fd-4f5b-b04c-4de463bdbea8'	System	09 Aug 2020 23:19:51
User entered 'Yes (Y)'	System	09 Aug 2020 23:19:51

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:55:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-09T18:19:38', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '1f8f3e39-e1fd-4f5b-b04c-4de463bdbea8'	System	09 Aug 2020 23:19:51
User entered '98.8'	System	09 Aug 2020 23:19:51

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-09T18:19:42', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '1f8f3e39-e1fd-4f5b-b04c-4de463bdbea8'	System	09 Aug 2020 23:19:51
User entered 'No (N)'	System	09 Aug 2020 23:19:51

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:55:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-09T18:19:49', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '1f8f3e39-e1fd-4f5b-b04c-4de463bdbea8'	System	09 Aug 2020 23:19:51
User entered '09 Aug 2020 18:19'	System	09 Aug 2020 23:19:51

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 16:35:18
User entered 'Day 5'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:55:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-10T22:24:49', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '8ffaa7c8-4121-47fd-a00c-dae35a977452'	System	11 Aug 2020 03:26:41
User entered 'Yes (Y)'	System	11 Aug 2020 03:26:41

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:55:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-10T22:25:05', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '8ffaa7c8-4121-47fd-a00c-dae35a977452'	System	11 Aug 2020 03:26:41
User entered '99.0'	System	11 Aug 2020 03:26:41

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-10T22:25:08', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '8ffaa7c8-4121-47fd-a00c-dae35a977452'	System	11 Aug 2020 03:26:41
User entered 'No (N)'	System	11 Aug 2020 03:26:41

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:55:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-10T22:26:40', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '8ffaa7c8-4121-47fd-a00c-dae35a977452'	System	11 Aug 2020 03:26:41
User entered '10 Aug 2020 22:26'	System	11 Aug 2020 03:26:41

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 16:35:18
User entered 'Day 6'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:55:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-12T08:58:45', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '9162bc01-10bf-42cd-bc3f-fb56e11025cf'	System	12 Aug 2020 13:59:08
User entered 'Yes (Y)'	System	12 Aug 2020 13:59:08

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:55:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-12T08:59:00', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '9162bc01-10bf-42cd-bc3f-fb56e11025cf'	System	12 Aug 2020 13:59:08
User entered '98.9'	System	12 Aug 2020 13:59:08

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-12T08:59:02', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '9162bc01-10bf-42cd-bc3f-fb56e11025cf'	System	12 Aug 2020 13:59:08
User entered 'No (N)'	System	12 Aug 2020 13:59:08

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:55:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-12T08:59:06', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '9162bc01-10bf-42cd-bc3f-fb56e11025cf'	System	12 Aug 2020 13:59:08
User entered '12 Aug 2020 08:59'	System	12 Aug 2020 13:59:08

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 16:35:18
User entered 'Day 7'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:55:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-12T19:55:50', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '0224d39c-c8a1-4aa2-93c1-995357244946'	System	13 Aug 2020 00:57:32
User entered 'Yes (Y)'	System	13 Aug 2020 00:57:32

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:55:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-12T19:57:24', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '0224d39c-c8a1-4aa2-93c1-995357244946'	System	13 Aug 2020 00:57:32
User entered '98.6'	System	13 Aug 2020 00:57:32

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-12T19:57:26', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '0224d39c-c8a1-4aa2-93c1-995357244946'	System	13 Aug 2020 00:57:32
User entered 'No (N)'	System	13 Aug 2020 00:57:32

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:55:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-12T19:57:28', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '0224d39c-c8a1-4aa2-93c1-995357244946'	System	13 Aug 2020 00:57:32
User entered '12 Aug 2020 19:57'	System	13 Aug 2020 00:57:32

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 16:35:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-06T11:36:34', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '10ae5614-59b0-48c8-bbe9-70aca34cc111'	System	06 Aug 2020 16:37:23
User entered 'None (1)'	System	06 Aug 2020 16:37:23

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-06T11:36:53', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '10ae5614-59b0-48c8-bbe9-70aca34cc111'	System	06 Aug 2020 16:37:23
User entered 'No (N)'	System	06 Aug 2020 16:37:23

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-06T11:36:58', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '10ae5614-59b0-48c8-bbe9-70aca34cc111'	System	06 Aug 2020 16:37:23
User entered 'No (N)'	System	06 Aug 2020 16:37:23

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-06T11:37:16', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '10ae5614-59b0-48c8-bbe9-70aca34cc111'	System	06 Aug 2020 16:37:23
User entered 'None (1)'	System	06 Aug 2020 16:37:23

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-06T11:37:19', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '10ae5614-59b0-48c8-bbe9-70aca34cc111'	System	06 Aug 2020 16:37:23
User entered '06 Aug 2020 11:37'	System	06 Aug 2020 16:37:23

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:17'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 13:47'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 16:35:18
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-06T23:09:31', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '050f8911-3659-4f31-b301-ba6fb4d9e4a6'	System	07 Aug 2020 04:10:36
User entered 'None (1)'	System	07 Aug 2020 04:10:36

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-06T23:09:42', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '050f8911-3659-4f31-b301-ba6fb4d9e4a6'	System	07 Aug 2020 04:10:36
User entered 'No (N)'	System	07 Aug 2020 04:10:36

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-06T23:10:03', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '050f8911-3659-4f31-b301-ba6fb4d9e4a6'	System	07 Aug 2020 04:10:36
User entered 'No (N)'	System	07 Aug 2020 04:10:36

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-06T23:10:31', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '050f8911-3659-4f31-b301-ba6fb4d9e4a6'	System	07 Aug 2020 04:10:36
User entered 'None (1)'	System	07 Aug 2020 04:10:36

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-06T23:10:34', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '050f8911-3659-4f31-b301-ba6fb4d9e4a6'	System	07 Aug 2020 04:10:36
User entered '06 Aug 2020 23:10'	System	07 Aug 2020 04:10:36

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 14:42'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 16:35:18
User entered 'Day 2'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:55:19

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-07T22:26:10', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '213bc0ed-9678-4e3e-a8a1-0fcc7e54fafa'	System	08 Aug 2020 03:26:31
User entered 'None (1)'	System	08 Aug 2020 03:26:31

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:55:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-07T22:26:14', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '213bc0ed-9678-4e3e-a8a1-0fcc7e54fafa'	System	08 Aug 2020 03:26:31
User entered 'No (N)'	System	08 Aug 2020 03:26:31

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-07T22:26:16', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '213bc0ed-9678-4e3e-a8a1-0fcc7e54fafa'	System	08 Aug 2020 03:26:31
User entered 'No (N)'	System	08 Aug 2020 03:26:31

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:55:19

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-07T22:26:24', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '213bc0ed-9678-4e3e-a8a1-0fcc7e54fafa' User entered 'None (1)'	System	08 Aug 2020 03:26:31
	System	08 Aug 2020 03:26:31

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:55:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-07T22:26:27', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '213bc0ed-9678-4e3e-a8a1-0fcc7e54fafa' User entered '07 Aug 2020 22:26'	System	08 Aug 2020 03:26:31

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 16:35:18
User entered 'Day 3'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:55:19

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-08T21:56:44', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '11e91b56-f122-4a8f-afee-3390c44eaa7b'	System	09 Aug 2020 02:57:21
User entered 'None (1)'	System	09 Aug 2020 02:57:21

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:55:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-08T21:56:55', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '11e91b56-f122-4a8f-afee-3390c44eaa7b'	System	09 Aug 2020 02:57:21
User entered 'No (N)'	System	09 Aug 2020 02:57:21

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-08T21:56:58', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '11e91b56-f122-4a8f-afee-3390c44eaa7b'	System	09 Aug 2020 02:57:21
User entered 'No (N)'	System	09 Aug 2020 02:57:21

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:55:19

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-08T21:57:16', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '11e91b56-f122-4a8f-afee-3390c44eaa7b'	System	09 Aug 2020 02:57:21
User entered 'None (1)'	System	09 Aug 2020 02:57:21

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:55:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-08T21:57:19', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '11e91b56-f122-4a8f-afee-3390c44eaa7b'	System	09 Aug 2020 02:57:21
User entered '08 Aug 2020 21:57'	System	09 Aug 2020 02:57:21

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 16:35:18
User entered 'Day 4'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:55:19

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-09T17:37:57', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '5aaf1e4d-8c22-4fe0-9244-8532b8ea6b0b'	System	09 Aug 2020 22:38:28
User entered 'None (1)'	System	09 Aug 2020 22:38:28

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:55:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-09T17:38:00', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '5aaf1e4d-8c22-4fe0-9244-8532b8ea6b0b'	System	09 Aug 2020 22:38:28
User entered 'No (N)'	System	09 Aug 2020 22:38:28

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-09T17:38:04', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '5aaf1e4d-8c22-4fe0-9244-8532b8ea6b0b'	System	09 Aug 2020 22:38:28
User entered 'No (N)'	System	09 Aug 2020 22:38:28

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:55:19

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-09T17:38:24', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '5aaf1e4d-8c22-4fe0-9244-8532b8ea6b0b'	System	09 Aug 2020 22:38:28
User entered 'None (1)'	System	09 Aug 2020 22:38:28

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:55:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-09T17:38:26', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '5aaf1e4d-8c22-4fe0-9244-8532b8ea6b0b' User entered '09 Aug 2020 17:38'	System	09 Aug 2020 22:38:28
	System	09 Aug 2020 22:38:28

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 16:35:18
User entered 'Day 5'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:55:19

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-10T19:14:57', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '31d1a254-41c5-4ba8-b904-7198336ea2f1'	System	11 Aug 2020 00:15:16
User entered 'None (1)'	System	11 Aug 2020 00:15:16

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:55:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-10T19:14:59', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '31d1a254-41c5-4ba8-b904-7198336ea2f1'	System	11 Aug 2020 00:15:16
User entered 'No (N)'	System	11 Aug 2020 00:15:16

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-10T19:15:01', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '31d1a254-41c5-4ba8-b904-7198336ea2f1'	System	11 Aug 2020 00:15:16
User entered 'No (N)'	System	11 Aug 2020 00:15:16

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:55:19

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-10T19:15:10', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '31d1a254-41c5-4ba8-b904-7198336ea2f1'	System	11 Aug 2020 00:15:16
User entered 'None (1)'	System	11 Aug 2020 00:15:16

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:55:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-10T19:15:12', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '31d1a254-41c5-4ba8-b904-7198336ea2f1'	System	11 Aug 2020 00:15:16
User entered '10 Aug 2020 19:15'	System	11 Aug 2020 00:15:16

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 16:35:18
User entered 'Day 6'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:55:19

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-11T15:06:32', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '9466bc8e-d082-4750-b578-dd784a96f3d6'	System	11 Aug 2020 20:06:48
User entered 'None (1)'	System	11 Aug 2020 20:06:48

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:55:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-11T15:06:35', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '9466bc8e-d082-4750-b578-dd784a96f3d6'	System	11 Aug 2020 20:06:48
User entered 'No (N)'	System	11 Aug 2020 20:06:48

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-11T15:06:37', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '9466bc8e-d082-4750-b578-dd784a96f3d6'	System	11 Aug 2020 20:06:48
User entered 'No (N)'	System	11 Aug 2020 20:06:48

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:55:19

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-11T15:06:43', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '9466bc8e-d082-4750-b578-dd784a96f3d6'	System	11 Aug 2020 20:06:48
User entered 'None (1)'	System	11 Aug 2020 20:06:48

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:55:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-11T15:06:45', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '9466bc8e-d082-4750-b578-dd784a96f3d6'	System	11 Aug 2020 20:06:48
User entered '11 Aug 2020 15:06'	System	11 Aug 2020 20:06:48

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 16:35:18
User entered 'Day 7'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:55:19

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-12T19:55:17', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'd1e48646-ca00-48b9-8999-a188a4e974f3'	System	13 Aug 2020 00:55:32
User entered 'None (1)'	System	13 Aug 2020 00:55:32

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:55:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-12T19:55:19', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'd1e48646-ca00-48b9-8999-a188a4e974f3'	System	13 Aug 2020 00:55:32
User entered 'No (N)'	System	13 Aug 2020 00:55:32

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-12T19:55:22', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'd1e48646-ca00-48b9-8999-a188a4e974f3'	System	13 Aug 2020 00:55:32
User entered 'No (N)'	System	13 Aug 2020 00:55:32

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:55:19

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-12T19:55:27', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'd1e48646-ca00-48b9-8999-a188a4e974f3'	System	13 Aug 2020 00:55:32
User entered 'None (1)'	System	13 Aug 2020 00:55:32

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:55:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-12T19:55:30', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'd1e48646-ca00-48b9-8999-a188a4e974f3'	System	13 Aug 2020 00:55:32
User entered '12 Aug 2020 19:55'	System	13 Aug 2020 00:55:32

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 16:35:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-06T11:38:04', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'f9d9b2a6-2b85-4e38-bd53-4b756958177b'	System	06 Aug 2020 16:38:13
User entered 'None (0)'	System	06 Aug 2020 16:38:13

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-06T11:37:41', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'f9d9b2a6-2b85-4e38-bd53-4b756958177b'	System	06 Aug 2020 16:38:13
User entered 'None (0)'	System	06 Aug 2020 16:38:13

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-06T11:37:43', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'f9d9b2a6-2b85-4e38-bd53-4b756958177b'	System	06 Aug 2020 16:38:13
User entered 'None (0)'	System	06 Aug 2020 16:38:13

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-06T11:37:45', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'f9d9b2a6-2b85-4e38-bd53-4b756958177b'	System	06 Aug 2020 16:38:13
User entered 'None (0)'	System	06 Aug 2020 16:38:13

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-06T11:37:48', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'f9d9b2a6-2b85-4e38-bd53-4b756958177b'	System	06 Aug 2020 16:38:13
User entered 'None (0)'	System	06 Aug 2020 16:38:13

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-06T11:37:49', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'f9d9b2a6-2b85-4e38-bd53-4b756958177b'	System	06 Aug 2020 16:38:13
User entered 'None (0)'	System	06 Aug 2020 16:38:13

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-06T11:37:52', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'f9d9b2a6-2b85-4e38-bd53-4b756958177b'	System	06 Aug 2020 16:38:13
User entered 'No (N)'	System	06 Aug 2020 16:38:13

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-06T11:38:10', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'f9d9b2a6-2b85-4e38-bd53-4b756958177b'	System	06 Aug 2020 16:38:13
User entered '06 Aug 2020 11:38'	System	06 Aug 2020 16:38:13

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:17'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 13:47'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 16:35:18
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-06T23:08:54', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '5f47fca2-729a-438e-a973-b030c66b1c20'	System	07 Aug 2020 04:09:23
User entered 'None (0)'	System	07 Aug 2020 04:09:23

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-06T23:08:59', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '5f47fca2-729a-438e-a973-b030c66b1c20'	System	07 Aug 2020 04:09:23
User entered 'None (0)'	System	07 Aug 2020 04:09:23

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-06T23:09:05', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '5f47fca2-729a-438e-a973-b030c66b1c20'	System	07 Aug 2020 04:09:23
User entered 'None (0)'	System	07 Aug 2020 04:09:23

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-06T23:09:08', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '5f47fca2-729a-438e-a973-b030c66b1c20'	System	07 Aug 2020 04:09:23
User entered 'None (0)'	System	07 Aug 2020 04:09:23

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-06T23:09:10', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '5f47fca2-729a-438e-a973-b030c66b1c20'	System	07 Aug 2020 04:09:23
User entered 'None (0)'	System	07 Aug 2020 04:09:23

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-06T23:09:13', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '5f47fca2-729a-438e-a973-b030c66b1c20'	System	07 Aug 2020 04:09:23
User entered 'None (0)'	System	07 Aug 2020 04:09:23

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-06T23:09:18', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '5f47fca2-729a-438e-a973-b030c66b1c20'	System	07 Aug 2020 04:09:23
User entered 'No (N)'	System	07 Aug 2020 04:09:23

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-06T23:09:22', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '5f47fca2-729a-438e-a973-b030c66b1c20'	System	07 Aug 2020 04:09:23
User entered '06 Aug 2020 23:09'	System	07 Aug 2020 04:09:23

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 14:42'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 16:35:18
User entered 'Day 2'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:55:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-07T21:50:47', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '1b89d894-f263-4497-8a6f-691b2515adc6'	System	08 Aug 2020 02:51:02
User entered 'None (0)'	System	08 Aug 2020 02:51:02

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:55:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-07T21:50:49', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '1b89d894-f263-4497-8a6f-691b2515adc6'	System	08 Aug 2020 02:51:02
User entered 'None (0)'	System	08 Aug 2020 02:51:02

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:55:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-07T21:50:51', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '1b89d894-f263-4497-8a6f-691b2515adc6'	System	08 Aug 2020 02:51:02
User entered 'None (0)'	System	08 Aug 2020 02:51:02

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:55:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-07T21:50:52', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '1b89d894-f263-4497-8a6f-691b2515adc6'	System	08 Aug 2020 02:51:02
User entered 'None (0)'	System	08 Aug 2020 02:51:02

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:55:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-07T21:50:54', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '1b89d894-f263-4497-8a6f-691b2515adc6'	System	08 Aug 2020 02:51:02
User entered 'None (0)'	System	08 Aug 2020 02:51:02

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:55:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-07T21:50:56', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '1b89d894-f263-4497-8a6f-691b2515adc6'	System	08 Aug 2020 02:51:02
User entered 'None (0)'	System	08 Aug 2020 02:51:02

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-07T21:50:58', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '1b89d894-f263-4497-8a6f-691b2515adc6'	System	08 Aug 2020 02:51:02
User entered 'No (N)'	System	08 Aug 2020 02:51:02

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:55:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-07T21:51:00', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '1b89d894-f263-4497-8a6f-691b2515adc6'	System	08 Aug 2020 02:51:02
User entered '07 Aug 2020 21:51'	System	08 Aug 2020 02:51:02

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:55:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 16:35:18
User entered 'Day 3'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:55:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-08T21:57:22', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'db942ad3-fcf3-49ba-8618-1d7ca1c0b129'	System	09 Aug 2020 02:57:38
User entered 'None (0)'	System	09 Aug 2020 02:57:38

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:55:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-08T21:57:24', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'db942ad3-fcf3-49ba-8618-1d7ca1c0b129'	System	09 Aug 2020 02:57:38
User entered 'None (0)'	System	09 Aug 2020 02:57:38

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:55:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-08T21:57:26', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'db942ad3-fcf3-49ba-8618-1d7ca1c0b129'	System	09 Aug 2020 02:57:38
User entered 'None (0)'	System	09 Aug 2020 02:57:38

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:55:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-08T21:57:28', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'db942ad3-fcf3-49ba-8618-1d7ca1c0b129'	System	09 Aug 2020 02:57:38
User entered 'None (0)'	System	09 Aug 2020 02:57:38

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:55:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-08T21:57:30', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'db942ad3-fcf3-49ba-8618-1d7ca1c0b129'	System	09 Aug 2020 02:57:38
User entered 'None (0)'	System	09 Aug 2020 02:57:38

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:55:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-08T21:57:31', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'db942ad3-fcf3-49ba-8618-1d7ca1c0b129'	System	09 Aug 2020 02:57:38
User entered 'None (0)'	System	09 Aug 2020 02:57:38

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-08T21:57:34', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'db942ad3-fcf3-49ba-8618-1d7ca1c0b129'	System	09 Aug 2020 02:57:38
User entered 'No (N)'	System	09 Aug 2020 02:57:38

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:55:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-08T21:57:36', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'db942ad3-fcf3-49ba-8618-1d7ca1c0b129'	System	09 Aug 2020 02:57:38
User entered '08 Aug 2020 21:57'	System	09 Aug 2020 02:57:38

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 16:35:18
User entered 'Day 4'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:55:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-09T17:37:37', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'a874fb9a-3310-41aa-a7e2-bd0bf8bfd480'	System	09 Aug 2020 22:37:55
User entered 'None (0)'	System	09 Aug 2020 22:37:55

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:55:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-09T17:37:39', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'a874fb9a-3310-41aa-a7e2-bd0bf8bfd480'	System	09 Aug 2020 22:37:55
User entered 'None (0)'	System	09 Aug 2020 22:37:55

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:55:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-09T17:37:41', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'a874fb9a-3310-41aa-a7e2-bd0bf8bfd480'	System	09 Aug 2020 22:37:55
User entered 'None (0)'	System	09 Aug 2020 22:37:55

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:55:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-09T17:37:44', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'a874fb9a-3310-41aa-a7e2-bd0bf8bfd480'	System	09 Aug 2020 22:37:55
User entered 'None (0)'	System	09 Aug 2020 22:37:55

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:55:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-09T17:37:45', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'a874fb9a-3310-41aa-a7e2-bd0bf8bfd480'	System	09 Aug 2020 22:37:55
User entered 'None (0)'	System	09 Aug 2020 22:37:55

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:55:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-09T17:37:47', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'a874fb9a-3310-41aa-a7e2-bd0bf8bfd480'	System	09 Aug 2020 22:37:55
User entered 'None (0)'	System	09 Aug 2020 22:37:55

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-09T17:37:49', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'a874fb9a-3310-41aa-a7e2-bd0bf8bfd480'	System	09 Aug 2020 22:37:55
User entered 'No (N)'	System	09 Aug 2020 22:37:55

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:55:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-09T17:37:51', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'a874fb9a-3310-41aa-a7e2-bd0bf8bfd480'	System	09 Aug 2020 22:37:55
User entered '09 Aug 2020 17:37'	System	09 Aug 2020 22:37:55

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 16:35:18
User entered 'Day 5'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:55:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-10T19:15:16', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'ec0a4fea-2c72-4e58-a490-c74571ee3285'	System	11 Aug 2020 00:15:30
User entered 'None (0)'	System	11 Aug 2020 00:15:30

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:55:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-10T19:15:17', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'ec0a4fea-2c72-4e58-a490-c74571ee3285'	System	11 Aug 2020 00:15:30
User entered 'None (0)'	System	11 Aug 2020 00:15:30

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:55:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-10T19:15:19', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'ec0a4fea-2c72-4e58-a490-c74571ee3285'	System	11 Aug 2020 00:15:30
User entered 'None (0)'	System	11 Aug 2020 00:15:30

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:55:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-10T19:15:21', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'ec0a4fea-2c72-4e58-a490-c74571ee3285'	System	11 Aug 2020 00:15:30
User entered 'None (0)'	System	11 Aug 2020 00:15:30

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:55:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-10T19:15:22', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'ec0a4fea-2c72-4e58-a490-c74571ee3285'	System	11 Aug 2020 00:15:30
User entered 'None (0)'	System	11 Aug 2020 00:15:30

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:55:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-10T19:15:24', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'ec0a4fea-2c72-4e58-a490-c74571ee3285'	System	11 Aug 2020 00:15:30
User entered 'None (0)'	System	11 Aug 2020 00:15:30

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-10T19:15:27', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'ec0a4fea-2c72-4e58-a490-c74571ee3285'	System	11 Aug 2020 00:15:30
User entered 'No (N)'	System	11 Aug 2020 00:15:30

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:55:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-10T19:15:29', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'ec0a4fea-2c72-4e58-a490-c74571ee3285'	System	11 Aug 2020 00:15:30
User entered '10 Aug 2020 19:15'	System	11 Aug 2020 00:15:30

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 16:35:18
User entered 'Day 6'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:55:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-11T15:06:19', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'e15f3d6b-5ddb-4c6a-9b6d-623c88b4b1f1'	System	11 Aug 2020 20:06:31
User entered 'None (0)'	System	11 Aug 2020 20:06:31

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:55:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-11T15:06:20', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'e15f3d6b-5ddb-4c6a-9b6d-623c88b4b1f1'	System	11 Aug 2020 20:06:31
User entered 'None (0)'	System	11 Aug 2020 20:06:31

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:55:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-11T15:06:22', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'e15f3d6b-5ddb-4c6a-9b6d-623c88b4b1f1'	System	11 Aug 2020 20:06:31
User entered 'None (0)'	System	11 Aug 2020 20:06:31

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:55:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-11T15:06:23', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'e15f3d6b-5ddb-4c6a-9b6d-623c88b4b1f1'	System	11 Aug 2020 20:06:31
User entered 'None (0)'	System	11 Aug 2020 20:06:31

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:55:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-11T15:06:25', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'e15f3d6b-5ddb-4c6a-9b6d-623c88b4b1f1'	System	11 Aug 2020 20:06:31
User entered 'None (0)'	System	11 Aug 2020 20:06:31

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:55:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-11T15:06:26', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'e15f3d6b-5ddb-4c6a-9b6d-623c88b4b1f1'	System	11 Aug 2020 20:06:31
User entered 'None (0)'	System	11 Aug 2020 20:06:31

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-11T15:06:27', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'e15f3d6b-5ddb-4c6a-9b6d-623c88b4b1f1'	System	11 Aug 2020 20:06:31
User entered 'No (N)'	System	11 Aug 2020 20:06:31

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:55:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-11T15:06:29', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'e15f3d6b-5ddb-4c6a-9b6d-623c88b4b1f1'	System	11 Aug 2020 20:06:31
User entered '11 Aug 2020 15:06'	System	11 Aug 2020 20:06:31

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 16:35:18
User entered 'Day 7'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:55:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-12T19:55:33', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '936ec076-d00b-48b6-bf87-d49a3b02cae9'	System	13 Aug 2020 00:55:47
User entered 'None (0)'	System	13 Aug 2020 00:55:47

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:55:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-12T19:55:35', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '936ec076-d00b-48b6-bf87-d49a3b02cae9'	System	13 Aug 2020 00:55:47
User entered 'None (0)'	System	13 Aug 2020 00:55:47

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:55:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-12T19:55:37', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '936ec076-d00b-48b6-bf87-d49a3b02cae9'	System	13 Aug 2020 00:55:47
User entered 'None (0)'	System	13 Aug 2020 00:55:47

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:55:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-12T19:55:39', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '936ec076-d00b-48b6-bf87-d49a3b02cae9'	System	13 Aug 2020 00:55:47
User entered 'None (0)'	System	13 Aug 2020 00:55:47

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:55:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-12T19:55:41', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '936ec076-d00b-48b6-bf87-d49a3b02cae9'	System	13 Aug 2020 00:55:47
User entered 'None (0)'	System	13 Aug 2020 00:55:47

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:55:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-12T19:55:42', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '936ec076-d00b-48b6-bf87-d49a3b02cae9'	System	13 Aug 2020 00:55:47
User entered 'None (0)'	System	13 Aug 2020 00:55:47

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-12T19:55:44', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '936ec076-d00b-48b6-bf87-d49a3b02cae9'	System	13 Aug 2020 00:55:47
User entered 'No (N)'	System	13 Aug 2020 00:55:47

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:55:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-08-12T19:55:46', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '936ec076-d00b-48b6-bf87-d49a3b02cae9'	System	13 Aug 2020 00:55:47
User entered '12 Aug 2020 19:55'	System	13 Aug 2020 00:55:47

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 16:35:18

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 16:35:18

US3812059

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	13 Aug 2020 20:10:50

US3812059

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Breanna Galibert (b) (4) (b) (4)	13 Aug 2020 20:10:50

US3812059

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Breanna Galibert (b) (4)	13 Aug 2020 20:10:50

US3812059

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	13 Aug 2020 20:10:50

US3812059

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	25 Aug 2020 22:30:49

US3812059

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 22:30:49

US3812059

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	25 Aug 2020 22:31:02

US3812059

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:19

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020'	Breanna Galibert (b) (4) (b) (4)	25 Aug 2020 22:31:02

US3812059

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Breanna Galibert (b) (4) (b) (4)	25 Aug 2020 22:31:02

US3812059

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	25 Aug 2020 22:31:02

US3812059

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	31 Aug 2020 17:18:20

US3812059

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 17:18:20

US3812059

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	31 Aug 2020 17:18:30

US3812059

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:19

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020'	Breanna Galibert (b) (4) (b) (4)	31 Aug 2020 17:18:30

US3812059

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Breanna Galibert (b) (4) (b) (4)	31 Aug 2020 17:18:30

US3812059

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	31 Aug 2020 17:18:30

US3812059

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	01 Sep 2020 20:39:57

US3812059

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 20:39:57

US3812059

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:55:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	01 Sep 2020 20:40:06

US3812059

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '01 Sep 2020' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	10 Nov 2020 17:39:49
User closed query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4)	
Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'Subject within window' (Site from System).	(b) (4), (b) (6)	11 Sep 2020 09:14:47
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	Anya Penly (b) (4)	04 Sep 2020 22:43:37
User entered '1 Sep 2020'	(b) (4)	
	System	01 Sep 2020 20:40:06
	Breanna Galibert (b) (4)	01 Sep 2020 20:40:06
	(b) (4)	

US3812059

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4) (b) (4)	01 Sep 2020 20:40:06

US3812059

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:55:19

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	01 Sep 2020 20:40:06

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:19

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Heather Cherniawski (b) (4)	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '01 Sep 2020' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	10 Nov 2020 17:40:00
User entered '1 Sep 2020'	Heather Cherniawski (b) (4)	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:19

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '14:36'	Heather Cherniawski (b) (4)	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '01 Sep 2020 14:36'	System	10 Nov 2020 17:40:00
User entered '1 Sep 2020 14:36'	System	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.4' F	Heather Cherniawski (b) (4)	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:19

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Heather Cherniawski (b) (4)	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:19

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '76'	Heather Cherniawski (b) (4)	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '12'	Heather Cherniawski (b) (4)	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '100'	Heather Cherniawski (b) (4)	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '60'	Heather Cherniawski (b) (4)	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:19

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Heather Cherniawski (b) (4)	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '01 Sep 2020' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	10 Nov 2020 17:40:00
User entered '1 Sep 2020'	Heather Cherniawski (b) (4)	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:19

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '15:47'	Heather Cherniawski (b) (4)	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '01 Sep 2020 15:47'	System	10 Nov 2020 17:40:00
User entered '1 Sep 2020 15:47'	System	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.3' F	Heather Cherniawski (b) (4)	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:19

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Heather Cherniawski (b) (4)	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:19

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '68'	Heather Cherniawski (b) (4)	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '16'	Heather Cherniawski (b) (4)	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '100'	Heather Cherniawski (b) (4)	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '72'	Heather Cherniawski (b) (4)	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:55:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Cherniawski (b) (4)	14 Sep 2020 22:05:14

US3812059

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:55:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	14 Sep 2020 22:05:14

US3812059

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:19

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	14 Sep 2020 22:06:23

US3812059

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:19

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '01 Sep 2020' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	10 Nov 2020 17:40:12
User entered '1 Sep 2020'	Heather Cherniawski (b) (4)	14 Sep 2020 22:06:23

US3812059

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:19

[Test performed](#)

Audit	User	Time (GMT)
User entered 'Urine (URINE)'	Heather Cherniawski (b) (4)	14 Sep 2020 22:06:23

US3812059

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:19

[Result](#)

Audit	User	Time (GMT)
User entered 'Negative (NEGATIVE)'	Heather Cherniawski (b) (4)	14 Sep 2020 22:06:23

US3812059

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:19

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	14 Sep 2020 22:06:23

US3812059

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:19

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	14 Sep 2020 22:06:23

US3812059

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:19

[Collection time](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: "Was FSH sample collected?" is blank, however collection time is recorded. Please review and update correctly, else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 12:35:53
Query 'Per CDM: "Was FSH sample collected?" is blank, however collection time is recorded. Please review and update correctly, else clarify. Thank you. ' answered with 'NO FSH COLLECTED NO TIME AND DATE TO ENTER' (Site from DM).	Heather Cherniawski (b) (4)	23 Sep 2020 20:19:37
User entered empty; reason for change Data Entry Error	Heather Cherniawski (b) (4)	23 Sep 2020 20:19:32
User opened query 'Per CDM: "Was FSH sample collected?" is blank, however collection time is recorded. Please review and update correctly, else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 10:30:51
User entered '14:50'	Heather Cherniawski (b) (4)	14 Sep 2020 22:06:23

US3812059

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 22:06:23

US3812059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:55:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	01 Sep 2020 20:40:21

US3812059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:55:19

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Sep 2020 20:40:21

US3812059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Sep 2020 20:40:21

US3812059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:55:19

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	01 Sep 2020 20:40:21

US3812059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:55:19

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '01 Sep 2020' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	10 Nov 2020 17:40:26
User entered '1 Sep 2020'	Breanna Galibert (b) (4)	01 Sep 2020 20:40:21

US3812059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '15:09'	Breanna Galibert (b) (4) (b) (4)	01 Sep 2020 20:40:21

US3812059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '01 Sep 2020 15:09'	System	10 Nov 2020 17:40:26
User entered '1 Sep 2020 15:09'	System	01 Sep 2020 20:40:21

US3812059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:55:19

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Breanna Galibert (b) (4) (b) (4)	01 Sep 2020 20:40:21

US3812059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	01 Sep 2020 20:40:21

US3812059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:55:19

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	01 Sep 2020 20:40:21

US3812059

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	14 Sep 2020 22:05:44

US3812059

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:19

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '01 Sep 2020' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	10 Nov 2020 17:40:33
User entered '1 Sep 2020'	Heather Cherniawski (b) (4)	14 Sep 2020 22:05:44

US3812059

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '14:55'	Heather Cherniawski (b) (4)	14 Sep 2020 22:05:44

US3812059

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '01 Sep 2020 14:55'	System	10 Nov 2020 17:40:33
User entered '1 Sep 2020 14:55'	System	14 Sep 2020 22:05:44

US3812059

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:55:19

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '01 Sep 2020' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	10 Nov 2020 17:40:40
User entered '1 Sep 2020'	Heather Cherniawski (b) (4)	14 Sep 2020 22:05:59

US3812059

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:55:19

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Heather Cherniawski (b) (4)	14 Sep 2020 22:05:59

US3812059

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:55:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	14 Sep 2020 22:05:59

US3812059

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '14:58'	Heather Cherniawski (b) (4)	14 Sep 2020 22:05:59

US3812059

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '01 Sep 2020 14:58'	System	10 Nov 2020 17:40:40
User entered '1 Sep 2020 14:58'	System	14 Sep 2020 22:05:59

US3812059

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:55:19

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Heather Cherniawski (b) (4)	14 Sep 2020 22:05:59

US3812059

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:55:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Cherniawski (b) (4)	14 Sep 2020 22:05:59

US3812059

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:55:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	14 Sep 2020 22:05:59

US3812059

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 22:05:59

US3812059

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	09 Sep 2020 11:56:18

US3812059

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 11:56:18

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:40:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-01T15:44:14', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'a7c38515-026c-46a6-aba3-1eb8b53ae6fa'	System	01 Sep 2020 20:44:28
User entered 'Yes (Y)'	System	01 Sep 2020 20:44:28

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-01T15:44:18', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'a7c38515-026c-46a6-aba3-1eb8b53ae6fa' User entered '98.3'	System	01 Sep 2020 20:44:28
	System	01 Sep 2020 20:44:28

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-01T15:44:20', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'a7c38515-026c-46a6-aba3-1eb8b53ae6fa'	System	01 Sep 2020 20:44:28
User entered 'No (N)'	System	01 Sep 2020 20:44:28

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-01T15:44:22', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'a7c38515-026c-46a6-aba3-1eb8b53ae6fa'	System	01 Sep 2020 20:44:28
User entered '01 Sep 2020 15:44'	System	01 Sep 2020 20:44:28

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 15:29'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 17:59'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:40:21
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-02T00:52:30', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '30af5a6b-2d72-4f51-bec5-d4c61aa1f109'	System	02 Sep 2020 05:52:53
User entered 'Yes (Y)'	System	02 Sep 2020 05:52:53

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-02T00:52:46', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '30af5a6b-2d72-4f51-bec5-d4c61aa1f109'	System	02 Sep 2020 05:52:53
User entered '98.4'	System	02 Sep 2020 05:52:53

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-02T00:52:49', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '30af5a6b-2d72-4f51-bec5-d4c61aa1f109'	System	02 Sep 2020 05:52:53
User entered 'No (N)'	System	02 Sep 2020 05:52:53

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-02T00:52:51', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '30af5a6b-2d72-4f51-bec5-d4c61aa1f109'	System	02 Sep 2020 05:52:53
User entered '02 Sep 2020 00:52'	System	02 Sep 2020 05:52:53

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 18:54'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:40:21
User entered 'Day 2'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:55:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-03T08:57:52', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '52dfa161-995b-4ea0-a7e8-88b103ffcdbc'	System	03 Sep 2020 13:58:21
User entered 'Yes (Y)'	System	03 Sep 2020 13:58:21

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:55:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-03T08:58:14', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '52dfa161-995b-4ea0-a7e8-88b103ffcdcb'	System	03 Sep 2020 13:58:21
User entered '98.5'	System	03 Sep 2020 13:58:21

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-03T08:58:17', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '52dfa161-995b-4ea0-a7e8-88b103ffcdcb'	System	03 Sep 2020 13:58:21
User entered 'No (N)'	System	03 Sep 2020 13:58:21

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:55:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-03T08:58:19', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '52dfa161-995b-4ea0-a7e8-88b103ffcdcb'	System	03 Sep 2020 13:58:21
User entered '03 Sep 2020 08:58'	System	03 Sep 2020 13:58:21

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:40:21
User entered 'Day 3'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:55:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-03T23:51:10', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'de4a82e5-dde1-4e69-b339-5106853c06c4'	System	04 Sep 2020 04:51:22
User entered 'Yes (Y)'	System	04 Sep 2020 04:51:22

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:55:19

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-03T23:51:17', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'de4a82e5-dde1-4e69-b339-5106853c06c4'	System	04 Sep 2020 04:51:22
User entered '98.5'	System	04 Sep 2020 04:51:22

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-03T23:51:19', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'de4a82e5-dde1-4e69-b339-5106853c06c4'	System	04 Sep 2020 04:51:22
User entered 'No (N)'	System	04 Sep 2020 04:51:22

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:55:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-03T23:51:21', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'de4a82e5-dde1-4e69-b339-5106853c06c4'	System	04 Sep 2020 04:51:22
User entered '03 Sep 2020 23:51'	System	04 Sep 2020 04:51:22

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:40:21
User entered 'Day 4'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:55:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-05T09:53:40', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'f8b5fda3-cad2-4b14-a522-7070eac742ee'	System	05 Sep 2020 14:54:01
User entered 'Yes (Y)'	System	05 Sep 2020 14:54:01

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:55:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-05T09:53:54', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'f8b5fda3-cad2-4b14-a522-7070eac742ee'	System	05 Sep 2020 14:54:01
User entered '98.8'	System	05 Sep 2020 14:54:01

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-05T09:53:57', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'f8b5fda3-cad2-4b14-a522-7070eac742ee'	System	05 Sep 2020 14:54:01
User entered 'No (N)'	System	05 Sep 2020 14:54:01

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:55:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-05T09:53:59', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'f8b5fda3-cad2-4b14-a522-7070eac742ee'	System	05 Sep 2020 14:54:01
User entered '05 Sep 2020 09:53'	System	05 Sep 2020 14:54:01

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:40:21
User entered 'Day 5'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:55:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-05T23:11:17', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '23248d4b-0bf3-46bd-91c0-0ccc9fb048d0'	System	06 Sep 2020 04:11:33
User entered 'Yes (Y)'	System	06 Sep 2020 04:11:33

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:55:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-05T23:11:24', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '23248d4b-0bf3-46bd-91c0-0ccc9fb048d0'	System	06 Sep 2020 04:11:33
User entered '98.9'	System	06 Sep 2020 04:11:33

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-05T23:11:27', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '23248d4b-0bf3-46bd-91c0-0ccc9fb048d0'	System	06 Sep 2020 04:11:33
User entered 'No (N)'	System	06 Sep 2020 04:11:33

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:55:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-05T23:11:29', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '23248d4b-0bf3-46bd-91c0-0ccc9fb048d0'	System	06 Sep 2020 04:11:33
User entered '05 Sep 2020 23:11'	System	06 Sep 2020 04:11:33

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:40:21
User entered 'Day 6'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:55:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-06T20:48:50', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'f5fb760b-8ca9-4edd-96ca-6942547a16e3'	System	07 Sep 2020 01:50:04
User entered 'Yes (Y)'	System	07 Sep 2020 01:50:04

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:55:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-06T20:49:54', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'f5fb760b-8ca9-4edd-96ca-6942547a16e3'	System	07 Sep 2020 01:50:04
User entered '99.3'	System	07 Sep 2020 01:50:04

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-06T20:49:57', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'f5fb760b-8ca9-4edd-96ca-6942547a16e3'	System	07 Sep 2020 01:50:04
User entered 'No (N)'	System	07 Sep 2020 01:50:04

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:55:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-06T20:49:59', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'f5fb760b-8ca9-4edd-96ca-6942547a16e3'	System	07 Sep 2020 01:50:04
User entered '06 Sep 2020 20:49'	System	07 Sep 2020 01:50:04

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:40:21
User entered 'Day 7'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:55:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-07T23:41:44', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '221db5bb-0f8b-452e-b470-2714c0752509'	System	08 Sep 2020 04:41:57
User entered 'Yes (Y)'	System	08 Sep 2020 04:41:57

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:55:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-07T23:41:49', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '221db5bb-0f8b-452e-b470-2714c0752509'	System	08 Sep 2020 04:41:57
User entered '99.0'	System	08 Sep 2020 04:41:57

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-07T23:41:51', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '221db5bb-0f8b-452e-b470-2714c0752509'	System	08 Sep 2020 04:41:57
User entered 'No (N)'	System	08 Sep 2020 04:41:57

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:55:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-07T23:41:54', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '221db5bb-0f8b-452e-b470-2714c0752509'	System	08 Sep 2020 04:41:57
User entered '07 Sep 2020 23:41'	System	08 Sep 2020 04:41:57

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:40:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-01T15:44:26', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'a5495700-6247-400f-9fdd-a00b685ca13e'	System	01 Sep 2020 20:44:46
User entered 'None (1)'	System	01 Sep 2020 20:44:46

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-01T15:44:34', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'a5495700-6247-400f-9fdd-a00b685ca13e'	System	01 Sep 2020 20:44:46
User entered 'No (N)'	System	01 Sep 2020 20:44:46

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-01T15:44:36', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'a5495700-6247-400f-9fdd-a00b685ca13e'	System	01 Sep 2020 20:44:46
User entered 'No (N)'	System	01 Sep 2020 20:44:46

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-01T15:44:41', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'a5495700-6247-400f-9fdd-a00b685ca13e'	System	01 Sep 2020 20:44:46
User entered 'None (1)'	System	01 Sep 2020 20:44:46

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-01T15:44:43', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'a5495700-6247-400f-9fdd-a00b685ca13e'	System	01 Sep 2020 20:44:46
User entered '01 Sep 2020 15:44'	System	01 Sep 2020 20:44:46

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 15:29'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 17:59'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:40:21
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-02T00:52:55', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '494b2dd4-ff4a-48df-aaa3-6c87c3a5094e'	System	02 Sep 2020 05:53:19
User entered 'None (1)'	System	02 Sep 2020 05:53:19

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-02T00:53:07', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '494b2dd4-ff4a-48df-aaa3-6c87c3a5094e'	System	02 Sep 2020 05:53:19
User entered 'No (N)'	System	02 Sep 2020 05:53:19

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-02T00:53:09', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '494b2dd4-ff4a-48df-aaa3-6c87c3a5094e'	System	02 Sep 2020 05:53:19
User entered 'No (N)'	System	02 Sep 2020 05:53:19

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-02T00:53:10', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '494b2dd4-ff4a-48df-aaa3-6c87c3a5094e'	System	02 Sep 2020 05:53:19
User entered 'None (1)'	System	02 Sep 2020 05:53:19

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-02T00:53:18', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '494b2dd4-ff4a-48df-aaa3-6c87c3a5094e'	System	02 Sep 2020 05:53:19
User entered '02 Sep 2020 00:53'	System	02 Sep 2020 05:53:19

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 18:54'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:40:21
User entered 'Day 2'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:55:19

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-03T08:57:30', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '315f0f6e-a765-481c-8f52-ae21e793d006'	System	03 Sep 2020 13:57:46
User entered 'None (1)'	System	03 Sep 2020 13:57:46

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:55:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-03T08:57:34', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '315f0f6e-a765-481c-8f52-ae21e793d006'	System	03 Sep 2020 13:57:46
User entered 'No (N)'	System	03 Sep 2020 13:57:46

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-03T08:57:35', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '315f0f6e-a765-481c-8f52-ae21e793d006'	System	03 Sep 2020 13:57:46
User entered 'No (N)'	System	03 Sep 2020 13:57:46

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:55:19

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-03T08:57:42', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '315f0f6e-a765-481c-8f52-ae21e793d006'	System	03 Sep 2020 13:57:46
User entered 'None (1)'	System	03 Sep 2020 13:57:46

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:55:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-03T08:57:43', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '315f0f6e-a765-481c-8f52-ae21e793d006'	System	03 Sep 2020 13:57:46
User entered '03 Sep 2020 08:57'	System	03 Sep 2020 13:57:46

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:40:21
User entered 'Day 3'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:55:19

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-03T23:50:51', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '4186fabf-765d-4b10-8910-1a922ef7d392'	System	04 Sep 2020 04:51:10
User entered 'None (1)'	System	04 Sep 2020 04:51:10

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:55:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-03T23:50:57', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '4186fabf-765d-4b10-8910-1a922ef7d392'	System	04 Sep 2020 04:51:10
User entered 'No (N)'	System	04 Sep 2020 04:51:10

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-03T23:51:00', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '4186fabf-765d-4b10-8910-1a922ef7d392'	System	04 Sep 2020 04:51:10
User entered 'No (N)'	System	04 Sep 2020 04:51:10

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:55:19

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-03T23:51:04', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '4186fabf-765d-4b10-8910-1a922ef7d392'	System	04 Sep 2020 04:51:10
User entered 'None (1)'	System	04 Sep 2020 04:51:10

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:55:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-03T23:51:06', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '4186fabf-765d-4b10-8910-1a922ef7d392'	System	04 Sep 2020 04:51:10
User entered '03 Sep 2020 23:51'	System	04 Sep 2020 04:51:10

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:40:21
User entered 'Day 4'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:55:19

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-05T09:53:14', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '6d243179-387a-4ecc-bb6d-585c969cbe83'	System	05 Sep 2020 14:53:38
User entered 'None (1)'	System	05 Sep 2020 14:53:38

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:55:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-05T09:53:17', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '6d243179-387a-4ecc-bb6d-585c969cbe83'	System	05 Sep 2020 14:53:38
User entered 'No (N)'	System	05 Sep 2020 14:53:38

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-05T09:53:20', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '6d243179-387a-4ecc-bb6d-585c969cbe83'	System	05 Sep 2020 14:53:38
User entered 'No (N)'	System	05 Sep 2020 14:53:38

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:55:19

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-05T09:53:25', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '6d243179-387a-4ecc-bb6d-585c969cbe83'	System	05 Sep 2020 14:53:38
User entered 'None (1)'	System	05 Sep 2020 14:53:38

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:55:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-05T09:53:35', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '6d243179-387a-4ecc-bb6d-585c969cbe83'	System	05 Sep 2020 14:53:38
User entered '05 Sep 2020 09:53'	System	05 Sep 2020 14:53:38

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:40:21
User entered 'Day 5'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:55:19

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-05T23:11:33', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '4aa206b6-31d1-4454-a366-65e02c8c3906'	System	06 Sep 2020 04:11:43
User entered 'None (1)'	System	06 Sep 2020 04:11:43

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:55:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-05T23:11:34', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '4aa206b6-31d1-4454-a366-65e02c8c3906'	System	06 Sep 2020 04:11:43
User entered 'No (N)'	System	06 Sep 2020 04:11:43

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-05T23:11:36', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '4aa206b6-31d1-4454-a366-65e02c8c3906'	System	06 Sep 2020 04:11:43
User entered 'No (N)'	System	06 Sep 2020 04:11:43

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:55:19

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-05T23:11:39', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '4aa206b6-31d1-4454-a366-65e02c8c3906'	System	06 Sep 2020 04:11:43
User entered 'None (1)'	System	06 Sep 2020 04:11:43

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:55:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-05T23:11:42', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '4aa206b6-31d1-4454-a366-65e02c8c3906'	System	06 Sep 2020 04:11:43
User entered '05 Sep 2020 23:11'	System	06 Sep 2020 04:11:43

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:40:21
User entered 'Day 6'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:55:19

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-06T20:48:37', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '76f7fbb4-c553-44b1-a16d-a39561aea71e'	System	07 Sep 2020 01:48:49
User entered 'None (1)'	System	07 Sep 2020 01:48:49

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:55:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-06T20:48:39', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '76f7fbb4-c553-44b1-a16d-a39561aea71e'	System	07 Sep 2020 01:48:49
User entered 'No (N)'	System	07 Sep 2020 01:48:49

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-06T20:48:41', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '76f7fbb4-c553-44b1-a16d-a39561aea71e'	System	07 Sep 2020 01:48:49
User entered 'No (N)'	System	07 Sep 2020 01:48:49

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:55:19

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-06T20:48:44', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '76f7fbb4-c553-44b1-a16d-a39561aea71e'	System	07 Sep 2020 01:48:49
User entered 'None (1)'	System	07 Sep 2020 01:48:49

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:55:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-06T20:48:46', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '76f7fbb4-c553-44b1-a16d-a39561aea71e'	System	07 Sep 2020 01:48:49
User entered '06 Sep 2020 20:48'	System	07 Sep 2020 01:48:49

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:40:21
User entered 'Day 7'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:55:19

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-07T21:33:29', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'f42ede5e-3525-432d-bc92-032073a27383'	System	08 Sep 2020 02:33:43
User entered 'None (1)'	System	08 Sep 2020 02:33:43

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:55:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-07T21:33:32', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'f42ede5e-3525-432d-bc92-032073a27383'	System	08 Sep 2020 02:33:43
User entered 'No (N)'	System	08 Sep 2020 02:33:43

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-07T21:33:34', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'f42ede5e-3525-432d-bc92-032073a27383'	System	08 Sep 2020 02:33:43
User entered 'No (N)'	System	08 Sep 2020 02:33:43

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:55:19

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-07T21:33:39', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'f42ede5e-3525-432d-bc92-032073a27383'	System	08 Sep 2020 02:33:43
User entered 'None (1)'	System	08 Sep 2020 02:33:43

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:55:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-07T21:33:41', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'f42ede5e-3525-432d-bc92-032073a27383'	System	08 Sep 2020 02:33:43
User entered '07 Sep 2020 21:33'	System	08 Sep 2020 02:33:43

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:40:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-01T15:44:46', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '0565b29a-14ff-4c20-b1e4-98b90262a99a'	System	01 Sep 2020 20:45:03
User entered 'None (0)'	System	01 Sep 2020 20:45:03

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-01T15:44:48', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '0565b29a-14ff-4c20-b1e4-98b90262a99a'	System	01 Sep 2020 20:45:03
User entered 'None (0)'	System	01 Sep 2020 20:45:03

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-01T15:44:50', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '0565b29a-14ff-4c20-b1e4-98b90262a99a'	System	01 Sep 2020 20:45:03
User entered 'None (0)'	System	01 Sep 2020 20:45:03

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-01T15:44:51', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '0565b29a-14ff-4c20-b1e4-98b90262a99a'	System	01 Sep 2020 20:45:03
User entered 'None (0)'	System	01 Sep 2020 20:45:03

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-01T15:44:53', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '0565b29a-14ff-4c20-b1e4-98b90262a99a'	System	01 Sep 2020 20:45:03
User entered 'None (0)'	System	01 Sep 2020 20:45:03

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-01T15:44:54', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '0565b29a-14ff-4c20-b1e4-98b90262a99a'	System	01 Sep 2020 20:45:03
User entered 'None (0)'	System	01 Sep 2020 20:45:03

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-01T15:44:56', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '0565b29a-14ff-4c20-b1e4-98b90262a99a'	System	01 Sep 2020 20:45:03
User entered 'No (N)'	System	01 Sep 2020 20:45:03

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-01T15:44:58', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '0565b29a-14ff-4c20-b1e4-98b90262a99a'	System	01 Sep 2020 20:45:03
User entered '01 Sep 2020 15:44'	System	01 Sep 2020 20:45:03

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 15:29'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 17:59'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:40:21
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-02T00:53:21', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '38ca687f-06a1-44fa-ab3d-a9a4ab7e1487'	System	02 Sep 2020 05:53:36
User entered 'None (0)'	System	02 Sep 2020 05:53:36

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-02T00:53:23', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '38ca687f-06a1-44fa-ab3d-a9a4ab7e1487'	System	02 Sep 2020 05:53:36
User entered 'None (0)'	System	02 Sep 2020 05:53:36

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-02T00:53:24', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '38ca687f-06a1-44fa-ab3d-a9a4ab7e1487'	System	02 Sep 2020 05:53:36
User entered 'None (0)'	System	02 Sep 2020 05:53:36

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-02T00:53:26', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '38ca687f-06a1-44fa-ab3d-a9a4ab7e1487'	System	02 Sep 2020 05:53:36
User entered 'None (0)'	System	02 Sep 2020 05:53:36

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-02T00:53:27', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '38ca687f-06a1-44fa-ab3d-a9a4ab7e1487'	System	02 Sep 2020 05:53:36
User entered 'None (0)'	System	02 Sep 2020 05:53:36

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-02T00:53:29', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '38ca687f-06a1-44fa-ab3d-a9a4ab7e1487'	System	02 Sep 2020 05:53:36
User entered 'None (0)'	System	02 Sep 2020 05:53:36

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-02T00:53:32', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '38ca687f-06a1-44fa-ab3d-a9a4ab7e1487'	System	02 Sep 2020 05:53:36
User entered 'No (N)'	System	02 Sep 2020 05:53:36

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-02T00:53:34', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '38ca687f-06a1-44fa-ab3d-a9a4ab7e1487'	System	02 Sep 2020 05:53:36
User entered '02 Sep 2020 00:53'	System	02 Sep 2020 05:53:36

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 18:54'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:40:21
User entered 'Day 2'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:55:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-03T08:56:58', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'f6a572c5-2ac4-4d59-90d4-00c77acc2854'	System	03 Sep 2020 13:57:18
User entered 'None (0)'	System	03 Sep 2020 13:57:18

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:55:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-03T08:57:00', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'f6a572c5-2ac4-4d59-90d4-00c77acc2854'	System	03 Sep 2020 13:57:18
User entered 'None (0)'	System	03 Sep 2020 13:57:18

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:55:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-03T08:57:01', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'f6a572c5-2ac4-4d59-90d4-00c77acc2854'	System	03 Sep 2020 13:57:18
User entered 'None (0)'	System	03 Sep 2020 13:57:18

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:55:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-03T08:57:03', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'f6a572c5-2ac4-4d59-90d4-00c77acc2854'	System	03 Sep 2020 13:57:18
User entered 'None (0)'	System	03 Sep 2020 13:57:18

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:55:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-03T08:57:04', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'f6a572c5-2ac4-4d59-90d4-00c77acc2854'	System	03 Sep 2020 13:57:18
User entered 'None (0)'	System	03 Sep 2020 13:57:18

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:55:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-03T08:57:05', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'f6a572c5-2ac4-4d59-90d4-00c77acc2854'	System	03 Sep 2020 13:57:18
User entered 'None (0)'	System	03 Sep 2020 13:57:18

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-03T08:57:14', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'f6a572c5-2ac4-4d59-90d4-00c77acc2854'	System	03 Sep 2020 13:57:18
User entered 'No (N)'	System	03 Sep 2020 13:57:18

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:55:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-03T08:57:16', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'f6a572c5-2ac4-4d59-90d4-00c77acc2854' User entered '03 Sep 2020 08:57'	System	03 Sep 2020 13:57:18
	System	03 Sep 2020 13:57:18

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:40:21
User entered 'Day 3'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:55:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-03T23:50:37', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'dba4609d-a643-4d31-bcc1-7a9920b22923'	System	04 Sep 2020 04:50:50
User entered 'None (0)'	System	04 Sep 2020 04:50:50

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:55:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-03T23:50:38', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'dba4609d-a643-4d31-bcc1-7a9920b22923'	System	04 Sep 2020 04:50:50
User entered 'None (0)'	System	04 Sep 2020 04:50:50

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:55:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-03T23:50:39', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'dba4609d-a643-4d31-bcc1-7a9920b22923'	System	04 Sep 2020 04:50:50
User entered 'None (0)'	System	04 Sep 2020 04:50:50

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:55:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-03T23:50:40', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'dba4609d-a643-4d31-bcc1-7a9920b22923'	System	04 Sep 2020 04:50:50
User entered 'None (0)'	System	04 Sep 2020 04:50:50

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:55:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-03T23:50:42', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'dba4609d-a643-4d31-bcc1-7a9920b22923'	System	04 Sep 2020 04:50:50
User entered 'None (0)'	System	04 Sep 2020 04:50:50

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:55:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-03T23:50:43', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'dba4609d-a643-4d31-bcc1-7a9920b22923'	System	04 Sep 2020 04:50:50
User entered 'None (0)'	System	04 Sep 2020 04:50:50

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-03T23:50:45', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'dba4609d-a643-4d31-bcc1-7a9920b22923'	System	04 Sep 2020 04:50:50
User entered 'No (N)'	System	04 Sep 2020 04:50:50

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:55:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-03T23:50:46', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'dba4609d-a643-4d31-bcc1-7a9920b22923'	System	04 Sep 2020 04:50:50
User entered '03 Sep 2020 23:50'	System	04 Sep 2020 04:50:50

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:40:21
User entered 'Day 4'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:55:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-05T09:52:57', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '2e85e613-582d-4e7b-ae0d-ab0e7778281d'	System	05 Sep 2020 14:53:11
User entered 'None (0)'	System	05 Sep 2020 14:53:11

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:55:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-05T09:52:58', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '2e85e613-582d-4e7b-ae0d-ab0e7778281d'	System	05 Sep 2020 14:53:11
User entered 'None (0)'	System	05 Sep 2020 14:53:11

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:55:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-05T09:53:02', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '2e85e613-582d-4e7b-ae0d-ab0e7778281d'	System	05 Sep 2020 14:53:11
User entered 'None (0)'	System	05 Sep 2020 14:53:11

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:55:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-05T09:53:03', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '2e85e613-582d-4e7b-ae0d-ab0e7778281d'	System	05 Sep 2020 14:53:11
User entered 'None (0)'	System	05 Sep 2020 14:53:11

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:55:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-05T09:53:05', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '2e85e613-582d-4e7b-ae0d-ab0e7778281d'	System	05 Sep 2020 14:53:11
User entered 'None (0)'	System	05 Sep 2020 14:53:11

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:55:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-05T09:53:07', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '2e85e613-582d-4e7b-ae0d-ab0e7778281d'	System	05 Sep 2020 14:53:11
User entered 'None (0)'	System	05 Sep 2020 14:53:11

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-05T09:53:08', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '2e85e613-582d-4e7b-ae0d-ab0e7778281d'	System	05 Sep 2020 14:53:11
User entered 'No (N)'	System	05 Sep 2020 14:53:11

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:55:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-05T09:53:10', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '2e85e613-582d-4e7b-ae0d-ab0e7778281d'	System	05 Sep 2020 14:53:11
User entered '05 Sep 2020 09:53'	System	05 Sep 2020 14:53:11

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:40:21
User entered 'Day 5'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:55:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-05T23:11:45', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'dbc11f5b-1982-473d-8615-469e1e9d326d'	System	06 Sep 2020 04:12:03
User entered 'None (0)'	System	06 Sep 2020 04:12:03

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:55:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-05T23:11:46', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'dbc11f5b-1982-473d-8615-469e1e9d326d'	System	06 Sep 2020 04:12:03
User entered 'None (0)'	System	06 Sep 2020 04:12:03

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:55:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-05T23:11:48', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'dbc11f5b-1982-473d-8615-469e1e9d326d'	System	06 Sep 2020 04:12:03
User entered 'None (0)'	System	06 Sep 2020 04:12:03

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:55:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-05T23:11:49', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'dbc11f5b-1982-473d-8615-469e1e9d326d'	System	06 Sep 2020 04:12:03
User entered 'None (0)'	System	06 Sep 2020 04:12:03

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:55:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-05T23:11:50', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'dbc11f5b-1982-473d-8615-469e1e9d326d'	System	06 Sep 2020 04:12:03
User entered 'None (0)'	System	06 Sep 2020 04:12:03

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:55:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-05T23:11:53', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'dbc11f5b-1982-473d-8615-469e1e9d326d'	System	06 Sep 2020 04:12:03
User entered 'None (0)'	System	06 Sep 2020 04:12:03

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-05T23:11:56', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'dbc11f5b-1982-473d-8615-469e1e9d326d'	System	06 Sep 2020 04:12:03
User entered 'No (N)'	System	06 Sep 2020 04:12:03

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:55:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-05T23:11:59', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'dbc11f5b-1982-473d-8615-469e1e9d326d'	System	06 Sep 2020 04:12:03
User entered '05 Sep 2020 23:11'	System	06 Sep 2020 04:12:03

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:40:21
User entered 'Day 6'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:55:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-06T20:48:21', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'fa556172-cce2-4323-871f-6fded65935d9'	System	07 Sep 2020 01:48:37
User entered 'None (0)'	System	07 Sep 2020 01:48:37

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:55:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-06T20:48:24', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'fa556172-cce2-4323-871f-6fded65935d9'	System	07 Sep 2020 01:48:37
User entered 'None (0)'	System	07 Sep 2020 01:48:37

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:55:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-06T20:48:26', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'fa556172-cce2-4323-871f-6fded65935d9'	System	07 Sep 2020 01:48:37
User entered 'None (0)'	System	07 Sep 2020 01:48:37

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:55:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-06T20:48:27', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'fa556172-cce2-4323-871f-6fded65935d9'	System	07 Sep 2020 01:48:37
User entered 'None (0)'	System	07 Sep 2020 01:48:37

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:55:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-06T20:48:28', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'fa556172-cce2-4323-871f-6fded65935d9'	System	07 Sep 2020 01:48:37
User entered 'None (0)'	System	07 Sep 2020 01:48:37

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:55:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-06T20:48:31', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'fa556172-cce2-4323-871f-6fded65935d9'	System	07 Sep 2020 01:48:37
User entered 'None (0)'	System	07 Sep 2020 01:48:37

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-06T20:48:32', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'fa556172-cce2-4323-871f-6fded65935d9'	System	07 Sep 2020 01:48:37
User entered 'No (N)'	System	07 Sep 2020 01:48:37

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:55:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-06T20:48:34', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'fa556172-cce2-4323-871f-6fded65935d9'	System	07 Sep 2020 01:48:37
User entered '06 Sep 2020 20:48'	System	07 Sep 2020 01:48:37

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:40:21
User entered 'Day 7'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:55:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-07T21:33:44', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'af746f59-ad92-434a-9c5e-474f395b6c6d'	System	08 Sep 2020 02:33:57
User entered 'None (0)'	System	08 Sep 2020 02:33:57

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:55:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-07T21:33:45', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'af746f59-ad92-434a-9c5e-474f395b6c6d'	System	08 Sep 2020 02:33:57
User entered 'None (0)'	System	08 Sep 2020 02:33:57

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:55:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-07T21:33:46', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'af746f59-ad92-434a-9c5e-474f395b6c6d'	System	08 Sep 2020 02:33:57
User entered 'None (0)'	System	08 Sep 2020 02:33:57

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:55:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-07T21:33:48', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'af746f59-ad92-434a-9c5e-474f395b6c6d'	System	08 Sep 2020 02:33:57
User entered 'None (0)'	System	08 Sep 2020 02:33:57

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:55:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-07T21:33:49', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'af746f59-ad92-434a-9c5e-474f395b6c6d'	System	08 Sep 2020 02:33:57
User entered 'None (0)'	System	08 Sep 2020 02:33:57

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:55:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-07T21:33:50', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'af746f59-ad92-434a-9c5e-474f395b6c6d'	System	08 Sep 2020 02:33:57
User entered 'None (0)'	System	08 Sep 2020 02:33:57

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-07T21:33:51', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'af746f59-ad92-434a-9c5e-474f395b6c6d'	System	08 Sep 2020 02:33:57
User entered 'No (N)'	System	08 Sep 2020 02:33:57

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:55:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-09-07T21:33:54', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'af746f59-ad92-434a-9c5e-474f395b6c6d' User entered '07 Sep 2020 21:33'	System	08 Sep 2020 02:33:57
	System	08 Sep 2020 02:33:57

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:55:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 20:40:21

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:55:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 20:40:21

US3812059

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	09 Sep 2020 11:56:28

US3812059

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:19

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	10 Nov 2020 17:41:00
User entered '8 Sep 2020'	Karen Knapp (b) (4)	09 Sep 2020 11:56:28

US3812059

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4) (b) (4)	09 Sep 2020 11:56:28

US3812059

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	09 Sep 2020 11:56:28

US3812059

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	13 Sep 2020 14:14:56

US3812059

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Sep 2020 14:14:56

US3812059

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	15 Sep 2020 20:39:30

US3812059

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:19

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	Karen Knapp (b) (4) (b) (4)	15 Sep 2020 20:39:30

US3812059

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4) (b) (4)	15 Sep 2020 20:39:30

US3812059

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	15 Sep 2020 20:39:30

US3812059

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	15 Sep 2020 20:39:34

US3812059

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 20:39:34

US3812059

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	22 Sep 2020 21:55:26

US3812059

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:19

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020'	Karen Knapp (b) (4) (b) (4)	22 Sep 2020 21:55:26

US3812059

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4) (b) (4)	22 Sep 2020 21:55:26

US3812059

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	22 Sep 2020 21:55:26

US3812059

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	22 Sep 2020 21:55:30

US3812059

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 21:55:30

US3812059

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:55:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	02 Oct 2020 15:46:48

US3812059

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '30 Sep 2020'	Breanna Galibert (b) (4) (b) (4)	02 Oct 2020 15:46:48

US3812059

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4) (b) (4)	02 Oct 2020 15:46:48

US3812059

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:55:19

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	02 Oct 2020 15:46:48

US3812059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	02 Oct 2020 15:47:17

US3812059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	Breanna Galibert (b) (4) (b) (4)	02 Oct 2020 15:47:17

US3812059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '15:56'	Breanna Galibert (b) (4) (b) (4)	02 Oct 2020 15:47:17

US3812059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '30 Sep 2020 15:56'	System	02 Oct 2020 15:47:17

US3812059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.1' F	Breanna Galibert (b) (4) (b) (4)	02 Oct 2020 15:47:17

US3812059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Breanna Galibert (b) (4) (b) (4)	02 Oct 2020 15:47:17

US3812059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	02 Oct 2020 15:47:17

US3812059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '92'	Breanna Galibert (b) (4) (b) (4)	02 Oct 2020 15:47:17

US3812059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Oct 2020 15:47:17

US3812059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '14'	Breanna Galibert (b) (4) (b) (4)	02 Oct 2020 15:47:17

US3812059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Oct 2020 15:47:17

US3812059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '102'	Breanna Galibert (b) (4) (b) (4)	02 Oct 2020 15:47:17

US3812059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Oct 2020 15:47:17

US3812059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '60'	Breanna Galibert (b) (4) (b) (4)	02 Oct 2020 15:47:17

US3812059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Oct 2020 15:47:17

US3812059

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:55:19

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	02 Oct 2020 15:47:28

US3812059

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:55:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	02 Oct 2020 15:47:28

US3812059

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	02 Oct 2020 15:47:51

US3812059

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:19

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 30Sep2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under Unscheduled visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. '(Site from DM).	(b) (4), (b) (6)	01 Nov 2020 16:38:13
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 30Sep2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under Unscheduled visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' answered with 'DATA IS CORRECT. UNSCHEDULE KIT WAS USED PER SPONSOR DUE TO NO SUPPLIES AVAILABLE ON SITE. PPD WAS NOTIFIED TO UPDATE' (Site from DM).	Angie Kean (b) (4) (b) (4)	26 Oct 2020 15:27:54
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 30Sep2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under Unscheduled visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. '(Site from DM).	(b) (4), (b) (6)	23 Oct 2020 12:23:27
User entered '30 Sep 2020'	Breanna Galibert (b) (4) (b) (4)	02 Oct 2020 15:47:51

US3812059

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '16:10'	Breanna Galibert (b) (4) (b) (4)	02 Oct 2020 15:47:51

US3812059

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '30 Sep 2020 16:10'	System	02 Oct 2020 15:47:51

US3812059

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	18 Oct 2020 15:28:41

US3812059

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Oct 2020 15:28:41

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 16:35:18
User entered 'Day 64'	System	06 Aug 2020 16:35:18

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[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 (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-10-08T11:35:22', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'a86a3b3a-f608-4598-a928-aaf15180c164' User entered 'No (N)'	System	08 Oct 2020 16:35:32

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-10-08T11:35:27', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'a86a3b3a-f608-4598-a928-aaf15180c164'	System	08 Oct 2020 16:35:32
User entered 'No (N)'	System	08 Oct 2020 16:35:32

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-10-08T11:35:30', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'a86a3b3a-f608-4598-a928-aaf15180c164' User entered '08 Oct 2020 11:35:30'	System	08 Oct 2020 16:35:32
	System	08 Oct 2020 16:35:32

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 16:35:18
User entered '06 Oct 2020 00:01'	System	06 Aug 2020 16:35:18

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 16:35:18
User entered '10 Oct 2020 23:59'	System	06 Aug 2020 16:35:18

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 16:35:18
User entered 'Day 71'	System	06 Aug 2020 16:35:18

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[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 (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-10-13T22:44:53', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'ad115958-147b-4dc4-92f3-e2d450259aee' User entered 'Yes (Y)'	System	14 Oct 2020 03:45:56
	System	14 Oct 2020 03:45:56

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-10-13T22:44:57', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'ad115958-147b-4dc4-92f3-e2d450259aee'	System	14 Oct 2020 03:45:56
User entered 'No (N)'	System	14 Oct 2020 03:45:56

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-10-13T22:45:05', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'ad115958-147b-4dc4-92f3-e2d450259aee' User entered 'Yes (Y)'	System	14 Oct 2020 03:45:56
	System	14 Oct 2020 03:45:56

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-10-13T22:45:22', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'ad115958-147b-4dc4-92f3-e2d450259aee' User entered '0'	System	14 Oct 2020 03:45:56
	System	14 Oct 2020 03:45:56

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-10-13T22:45:22', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'ad115958-147b-4dc4-92f3-e2d450259aee' User entered '1'	System	14 Oct 2020 03:45:56

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-10-13T22:45:22', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'ad115958-147b-4dc4-92f3-e2d450259aee' User entered '1'	System	14 Oct 2020 03:45:56

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-10-13T22:45:22', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'ad115958-147b-4dc4-92f3-e2d450259aee' User entered '0'	System	14 Oct 2020 03:45:56
	System	14 Oct 2020 03:45:56

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-10-13T22:45:22', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'ad115958-147b-4dc4-92f3-e2d450259aee' User entered '0'	System	14 Oct 2020 03:45:56
	System	14 Oct 2020 03:45:56

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-10-13T22:45:22', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'ad115958-147b-4dc4-92f3-e2d450259aee' User entered '1'	System	14 Oct 2020 03:45:56
	System	14 Oct 2020 03:45:56

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-10-13T22:45:22', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'ad115958-147b-4dc4-92f3-e2d450259aee'	System	14 Oct 2020 03:45:56
User entered '1'	System	14 Oct 2020 03:45:56

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-10-13T22:45:22', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'ad115958-147b-4dc4-92f3-e2d450259aee' User entered '1'	System	14 Oct 2020 03:45:56

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-10-13T22:45:22', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'ad115958-147b-4dc4-92f3-e2d450259aee' User entered '1'	System	14 Oct 2020 03:45:56

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-10-13T22:45:22', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'ad115958-147b-4dc4-92f3-e2d450259aee' User entered '0'	System	14 Oct 2020 03:45:56
	System	14 Oct 2020 03:45:56

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-10-13T22:45:22', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'ad115958-147b-4dc4-92f3-e2d450259aee' User entered '0'	System	14 Oct 2020 03:45:56
	System	14 Oct 2020 03:45:56

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-10-13T22:45:22', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'ad115958-147b-4dc4-92f3-e2d450259aee' User entered '1'	System	14 Oct 2020 03:45:56

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-10-13T22:45:22', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'ad115958-147b-4dc4-92f3-e2d450259aee' User entered '1'	System	14 Oct 2020 03:45:56

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-10-13T22:45:22', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'ad115958-147b-4dc4-92f3-e2d450259aee' User entered '1'	System	14 Oct 2020 03:45:56
	System	14 Oct 2020 03:45:56

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-10-13T22:45:22', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'ad115958-147b-4dc4-92f3-e2d450259aee' User entered '0'	System	14 Oct 2020 03:45:56

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-10-13T22:45:22', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'ad115958-147b-4dc4-92f3-e2d450259aee' User entered '0'	System	14 Oct 2020 03:45:56

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-10-13T22:45:22', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'ad115958-147b-4dc4-92f3-e2d450259aee' User entered '1'	System	14 Oct 2020 03:45:56

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-10-13T22:45:29', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'ad115958-147b-4dc4-92f3-e2d450259aee'	System	14 Oct 2020 03:45:56
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Oct 2020 03:45:56

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-10-13T22:45:37', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'ad115958-147b-4dc4-92f3-e2d450259aee'	System	14 Oct 2020 03:45:56
User entered 'Yes (Y)'	System	14 Oct 2020 03:45:56

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-10-13T22:45:41', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'ad115958-147b-4dc4-92f3-e2d450259aee'	System	14 Oct 2020 03:45:56
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Oct 2020 03:45:56

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-10-13T22:45:44', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'ad115958-147b-4dc4-92f3-e2d450259aee' User entered '13 Oct 2020 22:45:44'	System	14 Oct 2020 03:45:56
	System	14 Oct 2020 03:45:56

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 16:35:18
User entered '13 Oct 2020 00:01'	System	06 Aug 2020 16:35:18

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 16:35:18
User entered '17 Oct 2020 23:59'	System	06 Aug 2020 16:35:18

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 16:35:18
User entered 'Day 78'	System	06 Aug 2020 16:35:18

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-10-23T23:51:35', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'b0e221de-27ad-46ee-8007-6a7d4d4ecb8e'	System	24 Oct 2020 04:51:44
User entered 'No (N)'	System	24 Oct 2020 04:51:44

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

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 (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-10-23T23:51:39', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'b0e221de-27ad-46ee-8007-6a7d4d4ecb8e'	System	24 Oct 2020 04:51:44
User entered 'No (N)'	System	24 Oct 2020 04:51:44

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2020-10-23T23:51:42', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: 'b0e221de-27ad-46ee-8007-6a7d4d4ecb8e' User entered '23 Oct 2020 23:51:42'	System	24 Oct 2020 04:51:44
	System	24 Oct 2020 04:51:44

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 16:35:18
User entered '20 Oct 2020 00:01'	System	06 Aug 2020 16:35:18

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 16:35:18
User entered '24 Oct 2020 23:59'	System	06 Aug 2020 16:35:18

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '03 Oct 2020 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '07 Oct 2020 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '10 Oct 2020 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '14 Oct 2020 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '17 Oct 2020 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '21 Oct 2020 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '24 Oct 2020 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '28 Oct 2020 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '31 Oct 2020 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '04 Nov 2020 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '07 Nov 2020 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '11 Nov 2020 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '14 Nov 2020 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '18 Nov 2020 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 14:33:17

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:33:17
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	28 Oct 2020 19:27:55

US3812059

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:19

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020'	Karen Knapp (b) (4) (b) (4)	28 Oct 2020 19:27:55

US3812059

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4) (b) (4)	28 Oct 2020 19:27:55

US3812059

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	28 Oct 2020 19:27:55

US3812059

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	28 Oct 2020 19:27:59

US3812059

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 19:27:59

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:55:19

[Date of Contact](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	10 Nov 2020 17:42:14
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 13:12:15
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'UPDATED' (Site from DM).	Angie Kean (b) (4)	30 Oct 2020 22:38:48
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 12:57:38
User entered '8 Oct 2020'	Breanna Galibert (b) (4)	16 Oct 2020 22:45:44

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:55:19

[Time of Contact](#)

Audit	User	Time (GMT)
User entered '16:59'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:45:44

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:55:19

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 16:59'	System	10 Nov 2020 17:42:14
User entered '8 Oct 2020 16:59'	System	16 Oct 2020 22:45:44

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:55:19

[Type of Contact](#)

Audit	User	Time (GMT)
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Breanna Galibert (b) (4)	16 Oct 2020 22:45:44

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:55:19

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:45:44

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:55:19

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:46:49

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:55:19

[Date](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:46:49

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:55:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:46:49

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:55:19

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:46:49

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:55:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 22:46:49

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:55:19

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:46:49

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:55:19

[Chills](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:46:49

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:55:19

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:46:49

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:55:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:46:49

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:55:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:46:49

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:55:19

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:46:49

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:55:19

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:46:49

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:55:19

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:46:49

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:55:19

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:46:49

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:55:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:46:49

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:55:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:46:49

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:55:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:46:49

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:55:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:46:49

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:55:19

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:46:49

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:55:19

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:46:49

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:55:19

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:46:49

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:55:19

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:46:49

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:55:19

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:47:25

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:55:19

[Date](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:47:25

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:55:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:47:25

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:55:19

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:47:25

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:55:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 22:47:25

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:55:19

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:47:25

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:55:19

[Chills](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:47:25

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:55:19

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:47:25

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:55:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:47:25

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:55:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:47:25

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:55:19

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:47:25

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:55:19

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:47:25

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:55:19

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:47:25

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:55:19

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:47:25

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:55:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:47:25

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:55:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:47:25

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:55:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:47:25

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:55:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:47:25

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:55:19

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:47:25

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:55:19

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:47:25

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:55:19

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:47:25

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:55:19

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:47:25

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:55:19

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:48:03

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:55:19

[Date](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:48:03

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:55:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:48:03

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:55:19

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:48:03

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:55:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 22:48:03

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:55:19

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:48:03

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:55:19

[Chills](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:48:03

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:55:19

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:48:03

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:55:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:48:03

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:55:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:48:03

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:55:19

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:48:03

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:55:19

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:48:03

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:55:19

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:48:03

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:55:19

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:48:03

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:55:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:48:03

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:55:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:48:03

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:55:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:48:03

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:55:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:48:03

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:55:19

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:48:03

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:55:19

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:48:03

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:55:19

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:48:03

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:55:19

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:48:03

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:55:19

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 4)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:48:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:55:19

[Date](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:48:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:55:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:48:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:55:19

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:48:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:55:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 22:48:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:55:19

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:48:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:55:19

[Chills](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:48:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:55:19

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:48:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:55:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:48:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:55:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:48:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:55:19

Fatigue

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:48:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:55:19

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	16 Oct 2020 22:48:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:55:19

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:48:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:55:19

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:48:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:55:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:48:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:55:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:48:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:55:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:48:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:55:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:48:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:55:19

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:48:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:55:19

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:48:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:55:19

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:48:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:55:19

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:48:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:55:19

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:21

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:55:19

[Date](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:21

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:55:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:21

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:55:19

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:21

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:55:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 22:49:21

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:55:19

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:21

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:55:19

[Chills](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:21

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:55:19

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:21

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:55:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:21

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:55:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:21

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:55:19

Fatigue

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:21

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:55:19

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:21

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:55:19

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:21

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:55:19

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:21

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:55:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:21

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:55:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:21

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:55:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:21

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:55:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:21

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:55:19

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:21

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:55:19

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:21

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:55:19

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:21

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:55:19

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:21

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:55:19

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:55:19

[Date](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:55:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:55:19

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:55:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 22:49:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:55:19

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:55:19

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:55:19

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:55:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:55:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:55:19

Fatigue

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:55:19

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:55:19

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:55:19

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:55:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:55:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:55:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:55:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:55:19

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:55:19

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:55:19

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:55:19

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:55:19

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 7 (Day 7)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:54

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:55:19

[Date](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:54

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:55:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:54

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:55:19

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:54

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:55:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 22:49:54

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:55:19

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:54

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:55:19

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:54

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:55:19

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:54

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:55:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:54

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:55:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:54

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:55:19

Fatigue

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:54

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:55:19

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:54

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:55:19

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:54

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:55:19

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:54

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:55:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:54

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:55:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:54

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:55:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:54

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:55:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:54

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:55:19

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:54

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:55:19

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:54

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:55:19

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:54

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:55:19

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:49:54

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:55:19

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 8 (Day 8)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:09

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:55:19

[Date](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:09

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:55:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:09

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:55:19

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:09

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:55:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 22:50:09

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:55:19

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:09

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:55:19

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:09

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:55:19

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:09

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:55:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:09

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:55:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:09

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:55:19

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:09

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:55:19

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:09

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:55:19

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:09

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:55:19

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:09

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:55:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:09

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:55:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:09

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:55:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:09

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:55:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:09

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:55:19

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:09

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:55:19

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:09

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:55:19

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:09

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:55:19

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:09

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:55:19

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 9 (Day 9)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:33

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:55:19

[Date](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:33

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:55:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:33

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:55:19

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '98'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:33

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:55:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	16 Oct 2020 22:50:33

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:55:19

[Temperature](#)

Audit	User	Time (GMT)
User entered '99.1' F	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:33

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:55:19

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:33

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:55:19

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:33

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:55:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:33

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:55:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:33

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:55:19

Fatigue

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:33

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:55:19

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:33

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:55:19

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:33

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:55:19

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:33

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:55:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:33

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:55:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:33

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:55:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:33

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:55:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:33

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:55:19

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:33

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:55:19

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:33

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:55:19

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:33

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:55:19

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:50:33

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:55:19

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 10 (Day 10)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:55:19

[Date](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:55:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:55:19

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '97'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:55:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	20 Oct 2020 15:15:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:55:19

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.6' F	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:55:19

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:55:19

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:55:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:55:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:55:19

Fatigue

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:55:19

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:55:19

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:55:19

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:55:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:55:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:55:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:55:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:55:19

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:55:19

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:55:19

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:55:19

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:55:19

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 11 (Day 11)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:41

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:55:19

[Date](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:41

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:55:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:41

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:55:19

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '96'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:41

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:55:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	20 Oct 2020 15:15:41

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:55:19

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.6' F	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:41

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:55:19

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:41

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:55:19

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:41

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:55:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:41

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:55:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:41

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:55:19

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:41

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:55:19

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:41

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:55:19

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:41

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:55:19

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:41

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:55:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:41

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:55:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:41

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:55:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:41

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:55:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:41

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:55:19

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:41

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:55:19

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:41

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:55:19

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:41

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:55:19

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:15:41

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:55:19

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 12 (Day 12)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:16:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:55:19

[Date](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:16:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:55:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:16:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:55:19

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '97'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:16:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:55:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	20 Oct 2020 15:16:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:55:19

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.7' F	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:16:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:55:19

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:16:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:55:19

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:16:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:55:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:16:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:55:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:16:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:55:19

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:16:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:55:19

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:16:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:55:19

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:16:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:55:19

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:16:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:55:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:16:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:55:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:16:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:55:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:16:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:55:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:16:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:55:19

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:16:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:55:19

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:16:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:55:19

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:16:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:55:19

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	20 Oct 2020 15:16:15

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:55:19

[Date of Visit](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:51:02

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:55:19

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:51:02

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:55:19

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:51:02

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:55:19

[Date of Test](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:51:02

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:55:19

[Type of Test Performed](#)

Audit	User	Time (GMT)
User entered 'Nasopharyngeal Swab (NasopharyngealBreanna Galibert Swab)'	(b) (4) (b) (4)	16 Oct 2020 22:51:02

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:55:19

[Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:51:02

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:55:19

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:51:02

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:55:19

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
User entered 'BJC'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:51:02

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:55:19

[CLIA Certified?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	16 Oct 2020 22:51:02

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:55:19

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Oct 2020 22:51:02

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:55:19

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Cherniawski (b) (4)	26 Oct 2020 19:45:23

US3812059

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:55:19

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:38:26

US3812059

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:55:19

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:38:26

US3812059

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:55:19

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:38:26

US3812059

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:55:19

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:38:26

US3812059

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:55:19

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:38:26

US3812059

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:55:19

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:38:26

US3812059

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:55:19

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:38:26

US3812059

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:55:19

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:38:26

US3812059

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:55:19

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:38:26

US3812059

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:55:19

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:38:26

US3812059

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:55:19

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:38:26

US3812059

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:55:19

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:38:26

US3812059

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:55:19

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:38:26

US3812059

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:55:19

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:38:26

US3812059

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:55:19

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:38:26

US3812059

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:55:19

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:38:26

US3812059

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:55:19

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:38:26

US3812059

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:55:19

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:38:26

US3812059

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:55:19

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:38:26

US3812059

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:55:19

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:38:26

US3812059

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:55:19

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:38:26

US3812059

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:55:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:24:43

US3812059

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '16 Oct 2020'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:24:43

US3812059

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:24:43

US3812059

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:55:19

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	30 Oct 2020 22:24:43

US3812059

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:25:18

US3812059

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:25:18

US3812059

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '17:01'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:25:18

US3812059

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '16 Oct 2020 17:01'	System	30 Oct 2020 22:25:18

US3812059

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

Height (xxx.x)

Audit	User	Time (GMT)
User entered '64.8' in	Angie Kean (b) (4)	30 Oct 2020 22:25:18
DataPoint set to visible.	(b) (4) System	30 Oct 2020 22:24:43

US3812059

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '136.7' lb	Angie Kean (b) (4)	30 Oct 2020 22:25:18
DataPoint set to visible.	(b) (4) System	30 Oct 2020 22:24:43

US3812059

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '99.1' F	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:25:18

US3812059

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:25:18

US3812059

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:25:18

US3812059

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '86'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:25:18

US3812059

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Oct 2020 22:25:18

US3812059

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '14'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:25:18

US3812059

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Oct 2020 22:25:18

US3812059

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '96'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:25:18

US3812059

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Oct 2020 22:25:18

US3812059

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '70'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:25:18

US3812059

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Oct 2020 22:25:18

US3812059

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:55:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:25:30

US3812059

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:55:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:25:30

US3812059

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:55:19

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:25:38

US3812059

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:55:19

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:25:38

US3812059

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:55:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	04 Nov 2020 16:41:00

US3812059

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	04 Nov 2020 16:41:00

US3812059

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	04 Nov 2020 16:41:00

US3812059

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:55:19

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	04 Nov 2020 16:41:00

US3812059

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	04 Nov 2020 16:41:03

US3812059

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	04 Nov 2020 16:41:03

US3812059

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	04 Nov 2020 16:41:03

US3812059

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 16:41:03

US3812059

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	04 Nov 2020 16:41:03

US3812059

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	04 Nov 2020 16:41:03

US3812059

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	04 Nov 2020 16:41:03

US3812059

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

Pulse (xxx)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	04 Nov 2020 16:41:03

US3812059

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 16:41:03

US3812059

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	04 Nov 2020 16:41:03

US3812059

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 16:41:03

US3812059

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	04 Nov 2020 16:41:03

US3812059

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 16:41:03

US3812059

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	04 Nov 2020 16:41:03

US3812059

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 16:41:03

US3812059

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:55:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	04 Nov 2020 16:41:06

US3812059

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:55:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	04 Nov 2020 16:41:06

US3812059

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:55:19

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Breanna Galibert (b) (4) (b) (4)	04 Nov 2020 16:41:09

US3812059

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:55:19

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	04 Nov 2020 16:41:09

US3812059

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:55:19

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:31
User entered 'Yes (Y)' reason for change: New Information	Breanna Galibert (b) (4)	02 Oct 2020 15:44:03
User entered 'No (N)'	Karen Knapp (b) (4)	03 Sep 2020 12:36:34

US3812059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:19

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 21:10:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 21:10:48
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 15:46:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 15:46:48
Data point term sent to Coder	System	02 Oct 2020 15:46:09
User entered 'nausea'	Breanna Galibert (b) (4) (b) (4)	02 Oct 2020 15:45:09

US3812059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	02 Oct 2020 15:45:09

US3812059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'No (N)'	Breanna Galibert (b) (4)	02 Oct 2020 15:45:09
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	02 Oct 2020 15:45:09

US3812059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '23 Sep 2020'	Breanna Galibert (b) (4)	02 Oct 2020 15:45:09
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered empty.	Breanna Galibert (b) (4)	02 Oct 2020 15:45:09
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 15:45:09

US3812059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'No (N)'	Breanna Galibert (b) (4)	02 Oct 2020 15:45:09
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:19

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '23 Sep 2020'	Breanna Galibert (b) (4)	02 Oct 2020 15:45:09
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered empty.	Breanna Galibert (b) (4)	02 Oct 2020 15:45:09
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 15:45:09

US3812059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:19

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'Grade 1/Mild (Grade 1/Mild)'	Breanna Galibert (b) (4) (b) (4)	02 Oct 2020 15:45:09

US3812059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'No (N)'	Breanna Galibert (b) (4)	02 Oct 2020 15:45:09
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '0'	Breanna Galibert (b) (4)	02 Oct 2020 15:45:09
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '0'	Breanna Galibert (b) (4)	02 Oct 2020 15:45:09
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '0'	Breanna Galibert (b) (4) (b) (4)	02 Oct 2020 15:45:09

US3812059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:19

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered empty.	Breanna Galibert (b) (4)	02 Oct 2020 15:45:09
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:19

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered empty.	Breanna Galibert (b) (4)	02 Oct 2020 15:45:09
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered empty.	Breanna Galibert (b) (4)	02 Oct 2020 15:45:09
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered empty.	Breanna Galibert (b) (4)	02 Oct 2020 15:45:09
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '0'	Breanna Galibert (b) (4) (b) (4)	02 Oct 2020 15:45:09

US3812059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '0'	Breanna Galibert (b) (4)	02 Oct 2020 15:45:09
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '0'	Breanna Galibert (b) (4)	02 Oct 2020 15:45:09
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	02 Oct 2020 15:45:09

US3812059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	02 Oct 2020 15:45:09

US3812059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:19

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'Not Applicable (NOT APPLICABLE)'	Breanna Galibert (b) (4)	02 Oct 2020 15:45:09
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:19

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '1'	Breanna Galibert (b) (4)	02 Oct 2020 15:45:09
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '0'	Breanna Galibert (b) (4)	02 Oct 2020 15:45:09
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '0'	Breanna Galibert (b) (4)	02 Oct 2020 15:45:09
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:19

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Breanna Galibert (b) (4) (b) (4)	02 Oct 2020 15:45:09

US3812059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:19

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered empty.	Breanna Galibert (b) (4) (b) (4)	02 Oct 2020 15:45:09

US3812059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:19

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered empty.	Breanna Galibert (b) (4) (b) (4)	02 Oct 2020 15:45:09

US3812059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:19

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	02 Oct 2020 15:45:09

US3812059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:19

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Oct 2020 15:45:09

US3812059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:55:19

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 15:48:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 15:48:45
Data point term sent to Coder	System	02 Oct 2020 15:47:12
User entered 'vomiting'	Breanna Galibert (b) (4) (b) (4)	02 Oct 2020 15:46:32

US3812059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:55:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'No (N)'	Breanna Galibert (b) (4)	02 Oct 2020 15:46:32
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:55:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	02 Oct 2020 15:46:32

US3812059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:55:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'No (N)'	Breanna Galibert (b) (4)	02 Oct 2020 15:46:32
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '23 Sep 2020'	Breanna Galibert (b) (4)	02 Oct 2020 15:46:32
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered empty.	Breanna Galibert (b) (4)	02 Oct 2020 15:46:32
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:55:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 15:46:32

US3812059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:55:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'No (N)'	Breanna Galibert (b) (4)	02 Oct 2020 15:46:32
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:55:19

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '23 Sep 2020'	Breanna Galibert (b) (4)	02 Oct 2020 15:46:32
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:55:19

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered empty.	Breanna Galibert (b) (4)	02 Oct 2020 15:46:32
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:55:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 15:46:32

US3812059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:55:19

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'Grade 1/Mild (Grade 1/Mild)'	Breanna Galibert (b) (4) (b) (4)	02 Oct 2020 15:46:32

US3812059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:55:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'No (N)'	Breanna Galibert (b) (4)	02 Oct 2020 15:46:32
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:55:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '0'	Breanna Galibert (b) (4)	02 Oct 2020 15:46:32
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:55:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '0'	Breanna Galibert (b) (4)	02 Oct 2020 15:46:32
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:55:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '0'	Breanna Galibert (b) (4) (b) (4)	02 Oct 2020 15:46:32

US3812059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:55:19

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered empty.	Breanna Galibert (b) (4)	02 Oct 2020 15:46:32
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:55:19

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered empty.	Breanna Galibert (b) (4)	02 Oct 2020 15:46:32
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:55:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered empty.	Breanna Galibert (b) (4)	02 Oct 2020 15:46:32
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:55:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered empty.	Breanna Galibert (b) (4)	02 Oct 2020 15:46:32
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:55:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '0'	Breanna Galibert (b) (4) (b) (4)	02 Oct 2020 15:46:32

US3812059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:55:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '0'	Breanna Galibert (b) (4)	02 Oct 2020 15:46:32
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:55:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '0'	Breanna Galibert (b) (4)	02 Oct 2020 15:46:32
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:55:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	02 Oct 2020 15:46:32

US3812059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:55:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	02 Oct 2020 15:46:32

US3812059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:55:19

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'Not Applicable (NOT APPLICABLE)'	Breanna Galibert (b) (4)	02 Oct 2020 15:46:32
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:55:19

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '1'	Breanna Galibert (b) (4)	02 Oct 2020 15:46:32
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:55:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '0'	Breanna Galibert (b) (4)	02 Oct 2020 15:46:32
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:55:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '0'	Breanna Galibert (b) (4)	02 Oct 2020 15:46:32
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:55:19

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Breanna Galibert (b) (4)	02 Oct 2020 15:46:32

US3812059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:55:19

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered empty.	Breanna Galibert (b) (4) (b) (4)	02 Oct 2020 15:46:32

US3812059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:55:19

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered empty.	Breanna Galibert (b) (4)	02 Oct 2020 15:46:32
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:55:19

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	02 Oct 2020 15:46:32

US3812059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:55:19

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Oct 2020 15:46:32

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:53:26
User entered 'USA-US111-2020-mRNA-1273-P301000006'	System	29 Oct 2020 19:42:49
User entered 'New'	(b) (4), (b) (6)	29 Oct 2020 19:42:49

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:07:35
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety disorders NEC, PT: Anxiety disorder, LLT: Anxiety disorder - version MedDRA\23.0.	Coder Import (b) (4)	30 Oct 2020 20:14:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	30 Oct 2020 20:14:01
Data point term sent to Coder	System	30 Oct 2020 20:12:38
Coding entries removed.	Lyly Dang (b) (4)	30 Oct 2020 20:11:54
User entered 'Anxiety Disorder' reason for change: Data Entry Error	Lyly Dang (b) (4)	30 Oct 2020 20:11:54
User coded data point as SOC: Psychiatric disorders, HLGT: Manic and bipolar mood disorders and disturbances, HLT: Mood alterations with manic symptoms, PT: Mania, LLT: Manic episode - version MedDRA\23.0.	Coder Import (b) (4)	29 Oct 2020 20:14:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	29 Oct 2020 20:14:50
Data point term sent to Coder	System	28 Oct 2020 23:07:40
User entered "'Manic Episode'"	Lyly Dang (b) (4)	28 Oct 2020 23:06:52

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:07:37
User entered 'Yes (Y)'	Lyly Dang (b) (4)	28 Oct 2020 23:06:52

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'No (N)'	Lyly Dang (b) (4)	28 Oct 2020 23:06:52

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:07:39
User entered 'No (N)'	Lyly Dang (b) (4)	28 Oct 2020 23:06:52

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:07:40
User entered '24 Oct 2020' reason for change: New Information	Lyly Dang (b) (4)	30 Oct 2020 20:11:54
User entered '26 Oct 2020'	Lyly Dang (b) (4)	28 Oct 2020 23:06:52

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:07:42
User entered empty.	Lyly Dang (b) (4)	28 Oct 2020 23:06:52

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 23:06:52

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
DataPoint Un-verified.	Lyly Dang (b) (4)	14 Nov 2020 01:05:30
User entered 'No (N)' reason for change: New Information	Lyly Dang (b) (4)	14 Nov 2020 01:05:30
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:07:44
User entered 'Yes (Y)' reason for change: New Information	Lyly Dang (b) (4)	30 Oct 2020 20:11:54
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 23:12:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 23:12:21
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	28 Oct 2020 23:12:21
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 23:06:52
User entered empty.	Lyly Dang (b) (4)	28 Oct 2020 23:06:52

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
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).	(b) (4), (b) (6)	16 Nov 2020 16:14:52
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; discharge date of second hospitalization' (Site from Safety).	Lyly Dang (b) (4)	14 Nov 2020 01:05:58
DataPoint Un-verified.	Lyly Dang (b) (4)	14 Nov 2020 01:05:30
User entered '10 Nov 2020' reason for change: Data Entry Error	Lyly Dang (b) (4)	14 Nov 2020 01:05:30
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).	(b) (4), (b) (6)	06 Nov 2020 14:11:15
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:07:46
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	30 Oct 2020 20:12:18
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	30 Oct 2020 20:12:18
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	30 Oct 2020 20:11:54
User entered empty; reason for change Data Entry Error	Lyly Dang (b) (4)	30 Oct 2020 20:11:54
User entered '27 Oct 2020'	Lyly Dang (b) (4)	28 Oct 2020 23:06:52

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:07:51
User entered empty.	Lyly Dang (b) (4)	28 Oct 2020 23:06:52

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 23:06:52

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:07:48
User entered 'Grade 4 (Grade 4)'	Lyly Dang (b) (4)	28 Oct 2020 23:06:52

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:07:53
User entered 'Yes (Y)'	Lyly Dang (b) (4)	28 Oct 2020 23:06:52

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:07:55
User entered '0'	Lyly Dang (b) (4)	28 Oct 2020 23:06:52

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:07:57
User entered '0'	Lyly Dang (b) (4)	28 Oct 2020 23:06:52

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

[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)	19 Nov 2020 14:54:37
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:07:58
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 'Subject is still hospitalized' (Site from System).	Lyly Dang (b) (4)	30 Oct 2020 20:12:43
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	30 Oct 2020 20:11:54
User entered '1'	Lyly Dang (b) (4)	28 Oct 2020 23:06:52

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:08:02
User entered '26 Oct 2020'	Lyly Dang (b) (4)	28 Oct 2020 23:06:52

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 16:14:55
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'discharge date of second hospitalization' (Site from Safety).	Lyly Dang (b) (4)	14 Nov 2020 01:06:11
DataPoint Un-verified.	Lyly Dang (b) (4)	14 Nov 2020 01:05:30
User entered '10 Nov 2020' reason for change: New Information	Lyly Dang (b) (4)	14 Nov 2020 01:05:30
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 23:37:32
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:08:03
User entered empty; reason for change New Information	Lyly Dang (b) (4)	30 Oct 2020 20:11:54
User entered '27 Oct 2020'	Lyly Dang (b) (4)	28 Oct 2020 23:06:52

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:08:05
User entered 'No (N)'	Lyly Dang (b) (4)	28 Oct 2020 23:06:52

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:08:07
User entered empty.	Lyly Dang (b) (4)	28 Oct 2020 23:06:52

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:08:08
User entered '0'	Lyly Dang (b) (4)	28 Oct 2020 23:06:52

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:08:10
User entered '0'	Lyly Dang (b) (4)	28 Oct 2020 23:06:52

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:08:12
User entered '0'	Lyly Dang (b) (4)	28 Oct 2020 23:06:52

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:08:14
User entered 'Not Related (NOT RELATED)'	Lyly Dang (b) (4)	28 Oct 2020 23:06:52

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:08:17
User entered 'Not Related (NOT RELATED)'	Lyly Dang (b) (4)	28 Oct 2020 23:06:52

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:08:18
User entered 'Not Applicable (NOT APPLICABLE)'	Lyly Dang (b) (4)	28 Oct 2020 23:06:52

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:08:20
User entered '0'	Lyly Dang (b) (4)	28 Oct 2020 23:06:52

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:08:22
User entered '1'	Lyly Dang (b) (4)	28 Oct 2020 23:06:52

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:08:23
User entered '0'	Lyly Dang (b) (4)	28 Oct 2020 23:06:52

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 16:14:58
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	Lyly Dang (b) (4)	14 Nov 2020 01:06:20
DataPoint Un-verified.	Lyly Dang (b) (4)	14 Nov 2020 01:05:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Lyly Dang (b) (4)	14 Nov 2020 01:05:30
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 14:11:51
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:08:25
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Lyly Dang (b) (4)	30 Oct 2020 20:12:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Lyly Dang (b) (4)	28 Oct 2020 23:06:52

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:08:30
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 16:08:28
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:08:26
User entered empty.	Lyly Dang (b) (4)	28 Oct 2020 23:06:52

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User closed query 'PV Query: Please provide information for the second hospitalization, once information is available.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 16:15:01
Query 'PV Query: Please provide information for the second hospitalization, once information is available.' answered with 'updated' (Site from Safety).	Lyly Dang (b) (4)	14 Nov 2020 01:06:26
DataPoint Un-verified.	Lyly Dang (b) (4)	14 Nov 2020 01:05:30

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

[Narrative](#)

Audit	User	Time (GMT)
User entered "THIS IS A 21-YEAR-OLD FEMALE THAT PRESENTED IN THE ER ON 26OCT2020 PRESENTING WITH "BIZARRE BEHAVIOR". REPORTS NOT SLEEPING AND FEELINGS OF A PANIC ATTACK. SHE HAS A HISTORY OF TREATED ANXIETY AND DEPRESSION. ALSO, CURRENT LEFT EYE GLAUCOMA. SHE REPORTS SOCIAL ALCOHOL AND MARIJUANA USE. REPORTS NICOTINE DEPENDENCE. SHE HAS A HISTORY OF SEXUAL ASSAULT IN UNJAN2020 (b) (6) . SHE REPORTED INCREASED ANXIETY FOR THE FEW DAYS PRIOR TO THE ER VISIT, WHICH SHE TRIED TO SELF INCREASE SERTRALINE FROM 100 MG A DAY TO 150 MG A DAY. SHE WAS ULTIMATELY ADMITTED 26OCT2020 FOR THE FEELINGS OF MANIC AND HAVING AN IDENTITY CRISIS. SHE DENIED SUICIDAL OR HOMICIDAL FEELINGS. PERTINENT LABS INCLUDE NEGATIVE COVID PCR; POSITIVE CANNABINOIDS; AND ABNORMAL URINE ANALYSIS (1+ PROTEIN, 1+ KETONES, AND 2+ BLOOD). WHITE BLOOD CELL COUNT WAS INCREASED, 11.2. SHE WAS GIVEN ONE DOSE OF 25MG HYDROXYZINE AND SERTRALINE WAS DISCONTINUED. SHE WAS THOROUGHLY ASSESSED AND GIVEN A MENTAL STATUS EXAMINATION. SHE WAS GIVEN A DIAGNOSIS OF ANXIETY DISORDER. SHE WAS DISCHARGED IN STABLE CONDITION WITH AN ORDER TO START BUPROPION XL 150MG DAILY. SHE WAS ALSO GIVEN NICOTINE 14 MG TRANSDERMAL PATCH DAILY AND NICOTINE POLACRILEX 2MG GUM EVERY 2 HOURS AS NEEDED FOR NICOTINE ADDICTION. SHE AGREED TO A FOLLOW UP APPOINTMENT WITH PSYCHIATRY ON 16NOV2020. AFTER BEING DISCHARGED ON	Lyly Dang (b) (4)	14 Nov 2020 01:05:30

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

[Narrative](#)

Audit	User	Time (GMT)
OCT 27, 2020, THE SUBJECT WAS HOSPITALIZED TWO DAYS LATER AT MERCY BEHAVIORAL HEALTH FOR THE SAME DIAGNOSIS. MEDICAL RECORDS WERE REQUESTED. Upon review of medical records, the admitting diagnosis for the subject's second hospitalization was "severe episode of recurrent major depressive disorder." A separate SAE was created.' reason for change: Data Entry Error		
User opened query 'PV Query: Please provide information for the second hospitalization, once information is available.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 14:12:03
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:08:31

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

[Narrative](#)

Audit	User	Time (GMT)
User entered "THIS IS A 21-YEAR-OLD FEMALE THAT PRESENTED IN THE ER ON 26OCT2020 PRESENTING WITH "BIZARRE BEHAVIOR". REPORTS NOT SLEEPING AND FEELINGS OF A PANIC ATTACK. SHE HAS A HISTORY OF TREATED ANXIETY AND DEPRESSION. ALSO, CURRENT LEFT EYE GLAUCOMA. SHE REPORTS SOCIAL ALCOHOL AND MARIJUANA USE. REPORTS NICOTINE DEPENDENCE. SHE HAS A HISTORY OF SEXUAL ASSAULT IN UNJAN2020 (b) (6). SHE REPORTED INCREASED ANXIETY FOR THE FEW DAYS PRIOR TO THE ER VISIT, WHICH SHE TRIED TO SELF INCREASE SERTRALINE FROM 100 MG A DAY TO 150 MG A DAY. SHE WAS ULTIMATELY ADMITTED 26OCT2020 FOR THE FEELINGS OF MANIC AND HAVING AN IDENTITY CRISIS. SHE DENIED SUICIDAL OR HOMICIDAL FEELINGS. PERTINENT LABS INCLUDE NEGATIVE COVID PCR; POSITIVE CANNABINOIDS; AND ABNORMAL URINE ANALYSIS (1+ PROTEIN, 1+ KETONES, AND 2+ BLOOD). WHITE BLOOD CELL COUNT WAS INCREASED, 11.2. SHE WAS GIVEN ONE DOSE OF 25MG HYDROXYZINE AND SERTRALINE WAS DISCONTINUED. SHE WAS THOROUGHLY ASSESSED AND GIVEN A MENTAL STATUS EXAMINATION. SHE WAS GIVEN A DIAGNOSIS OF ANXIETY DISORDER. SHE WAS DISCHARGED IN STABLE CONDITION WITH AN ORDER TO START BUPROPION XL 150MG DAILY. SHE WAS ALSO GIVEN NICOTINE 14 MG TRANSDERMAL PATCH DAILY AND NICOTINE POLACRILEX 2MG GUM EVERY 2 HOURS AS NEEDED FOR NICOTINE ADDICTION. SHE AGREED TO A FOLLOW UP APPOINTMENT WITH PSYCHIATRY ON 16NOV2020. AFTER BEING DISCHARGED ON	Lyly Dang (b) (4)	01 Nov 2020 02:09:53

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

[Narrative](#)

Audit	User	Time (GMT)
OCT 27, 2020, THE SUBJECT WAS HOSPITALIZED TWO DAYS LATER AT MERCY BEHAVIORAL HEALTH FOR THE SAME DIAGNOSIS. MEDICAL RECORDS WERE REQUESTED.' reason for change: Data Entry Error		
User entered 'This is a 21-year-old female that presented in the ER on 26OCT2020 presenting with "bizarre behavior". Reports not sleeping and feelings of a panic attack. She has a history of treated anxiety and depression. Also, current left eye glaucoma. She reports social alcohol and marijuana use. Reports nicotine dependence. She has a history of sexual assault in UNJAN2020 (b) (6) (b) (6) . She reported increased anxiety for the few days prior to the ER visit, which she tried to self increase sertraline from 100 mg a day to 150 mg a day. She was ultimately admitted 26OCT2020 for the feelings of manic and having an identity crisis. She denied suicidal or homicidal feelings. Pertinent labs include negative COVID PCR; positive cannabinoids; and abnormal urine analysis (1+ protein, 1+ ketones, and 2+ blood). White blood cell count was increased, 11.2. She was given one dose of 25mg hydroxyzine and sertraline was discontinued. She was thoroughly assessed and given a mental status examination. She was given a diagnosis of Anxiety Disorder. She was discharged in stable condition with an order to start Bupropion XL 150mg daily. She was also given nicotine 14 mg transdermal patch daily and nicotine polacrilex 2mg gum every 2 hours as needed for Nicotine Addiction. She agreed to a follow up appointment with psychiatry on 16NOV2020. After being discharged on Oct 27, 2020, subject, the subject was hospitalized two days later at Mercy Behavioral Health for the same diagnosis. Medical records were requested.' reason for change: Data Entry Error	Lyly Dang (b) (4)	30 Oct 2020 20:11:54

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

[Narrative](#)

Audit	User	Time (GMT)
User entered 'During safety phone call, subject disclosed that she was hospitalized at Barnes Jewish Hospital for a "manic episode." Subject denies having an exacerbation of her anxiety or depression. Subject did not disclose any past medical history of having "manic episodes." Subject does not know what medications she received in the hospital other than Atarax and a nicotine patch. Medical records will be requested.'	Lyly Dang (b) (4)	28 Oct 2020 23:06:52

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 23:06:52

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 23:06:52

US3812059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:19

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Oct 2020 23:06:52

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:19

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User coded data point as SOC: Psychiatric disorders, HLGT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Nicotine dependence, LLT: Nicotine addiction - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Nov 2020 11:29:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Nov 2020 11:29:49
Data point term sent to Coder	System	01 Nov 2020 01:53:48
Coding entries removed.	Lyly Dang (b) (4)	01 Nov 2020 01:53:17
User entered 'WORSENING NICOTINE ADDICTION' reason for change: Data Entry Error	Lyly Dang (b) (4)	01 Nov 2020 01:53:17
User coded data point as SOC: Psychiatric disorders, HLGT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Nicotine dependence, LLT: Nicotine addiction - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 22:42:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 22:42:05
Data point term sent to Coder	System	30 Oct 2020 22:41:29
User entered 'NICOTINE ADDICTION'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:41:01

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:41:01

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:41:01

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:41:01

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '27 Oct 2020'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:41:01

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:19

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered empty.	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:41:01

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 22:41:01

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:41:01

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:19

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered empty.	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:41:01

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered empty.	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:41:01

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 22:41:01

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:19

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:41:01

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:41:01

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '0'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:41:01

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '0'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:41:01

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '0'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:41:01

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:19

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered empty.	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:41:01

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:19

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered empty.	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:41:01

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered empty.	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:41:01

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered empty.	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:41:01

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '0'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:41:01

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '0'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:41:01

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '0'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:41:01

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'Not Related (NOT RELATED)'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:41:01

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'Not Related (NOT RELATED)'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:41:01

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:19

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'Not Applicable (NOT APPLICABLE)'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:41:01

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:19

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '0'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:41:01

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '1'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:41:01

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '0'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:41:01

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:19

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:41:01

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:19

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered empty.	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:41:01

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:19

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered empty.	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:41:01

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:19

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	30 Oct 2020 22:41:01

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:19

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 22:41:01

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:16:20
User entered	(b) (4), (b) (6)	16 Nov 2020 16:16:15
'USA-US111-2020-mRNA-1273-P301000006'		

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User coded data point as SOC: Psychiatric disorders, HLT: Depressed mood disorders and disturbances, LLT: Major depressive disorder, recurrent episode - version MedDRA\\23.0.	Coder Import (b) (4)	14 Nov 2020 05:13:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	(b) (4)	14 Nov 2020 05:13:44
Data point term sent to Coder	System	14 Nov 2020 01:16:02
User entered 'Severe episode of recurrent major depressive disorder'	Lyly Dang (b) (4)	14 Nov 2020 01:15:36

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered 'Yes (Y)'	Lyly Dang (b) (4)	14 Nov 2020 01:15:36

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered 'No (N)'	Lyly Dang (b) (4)	14 Nov 2020 01:15:36

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered 'No (N)'	Lyly Dang (b) (4)	14 Nov 2020 01:15:36

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered '29 Oct 2020'	Lyly Dang (b) (4)	14 Nov 2020 01:15:36

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered empty.	Lyly Dang (b) (4)	14 Nov 2020 01:15:36

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 01:15:36

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered 'No (N)'	Lyly Dang (b) (4)	14 Nov 2020 01:15:36

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered '10 Nov 2020'	Lyly Dang (b) (4)	14 Nov 2020 01:15:36

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered empty.	Lyly Dang (b) (4)	14 Nov 2020 01:15:36

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 01:15:36

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered 'Grade 4 (Grade 4)'	Lyly Dang (b) (4)	14 Nov 2020 01:15:36

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered 'Yes (Y)'	Lyly Dang (b) (4)	14 Nov 2020 01:15:36

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered '0'	Lyly Dang (b) (4)	14 Nov 2020 01:15:36

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered '0'	Lyly Dang (b) (4)	14 Nov 2020 01:15:36

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered '1'	Lyly Dang (b) (4)	14 Nov 2020 01:15:36

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered '29 Oct 2020'	Lyly Dang (b) (4)	14 Nov 2020 01:15:36

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered '10 Nov 2020'	Lyly Dang (b) (4)	14 Nov 2020 01:15:36

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered 'No (N)'	Lyly Dang (b) (4)	14 Nov 2020 01:15:36

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered empty.	Lyly Dang (b) (4)	14 Nov 2020 01:15:36

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered '0'	Lyly Dang (b) (4)	14 Nov 2020 01:15:36

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered '0'	Lyly Dang (b) (4)	14 Nov 2020 01:15:36

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered '0'	Lyly Dang (b) (4)	14 Nov 2020 01:15:36

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered 'Not Related (NOT RELATED)'	Lyly Dang (b) (4)	14 Nov 2020 01:15:36

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered 'Not Related (NOT RELATED)'	Lyly Dang (b) (4)	14 Nov 2020 01:15:36

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered 'Not Applicable (NOT APPLICABLE)'	Lyly Dang (b) (4)	14 Nov 2020 01:15:36

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered '0'	Lyly Dang (b) (4)	14 Nov 2020 01:15:36

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered '1'	Lyly Dang (b) (4)	14 Nov 2020 01:15:36

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered '0'	Lyly Dang (b) (4)	14 Nov 2020 01:15:36

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Lyly Dang (b) (4)	14 Nov 2020 01:15:36

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered empty.	Lyly Dang (b) (4)	14 Nov 2020 01:15:36

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

[Narrative](#)

Audit	User	Time (GMT)
User entered "This was previously submitted via fax as "Anxiety disorder." THIS IS A 21 YEAR OLD FEMALE THAT PRESENTED WITH A COMPLAINT OF "PERSONAL PLEA FOR INSANITY." SUBJECT WAS INVOLUNTARILY ADMITTED TO HOSPITAL ON 29OCT2020 FOR MOOD DYSREGULATION AND BEHAVIORAL DISTURBANCES. THE SUBJECT'S INVOLUNTARY ADMISSION ENDED ON 05 NOVEMBER 2020, AS THE SUBJECT AGREED TO STAY IN THE HOSPITAL FOR MEDICATION ADJUSTMENT AND STABILIZATION. THIS SUBJECT HAS A PAST MEDICAL HISTORY CONSISTING OF POST TRAUMATIC STRESS DISORDER, GENERALIZED ANXIETY DISORDER, DISSOCIATIVE DISORDER, ALCOHOL ABUSE, AND CANNABIS ABUSE. SHE WAS RECENTLY HOSPITALIZED 26OCT2020 TO 27OCT2020 FOR ANXIETY DISORDER. PERTINENT LABS INCLUDE POSITIVE FOR CANNABINOIDS PER URINE DRUG SCREEN. DURING THIS STAY SHE SHOWED SIGNS OF DISSOCIATION, DELUSION, PARANOIA, FEELINGS OF ANXIETY, FAIR SLEEP, AND FAIR APPETITE. SHE DENIED FEELINGS OF SUICIDE OR HOMICIDAL IDEATION. SHE WAS COMPLIANT WITH MEDICATIONS THROUGHOUT STAY. SHE ATTENDED MULTIPLE PSYCHO-SPIRITUAL EDUCATION GROUPS TO HELP LEARN COPING SKILLS. SHE WAS GIVEN A PRIMARY DIAGNOSIS OF SEVERE EPISODE OF RECURRENT MAJOR DEPRESSIVE DISORDER. ALSO GIVEN A DIAGNOSIS OF DISSOCIATIVE DISORDER RELATED TO PTSD. SHE WAS DISCHARGED ON 10NOV2020 AFTER SIGNIFICANT IMPROVEMENT AND IN STABLE CONDITION. DISCHARGE MEDICATIONS GIVEN INCLUDE BUPROPION HCL ER 150MG DAILY, CHLORPROMAZINE 100MG EVERY 4 HOURS	Lyly Dang (b) (4)	14 Nov 2020 01:49:34

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

[Narrative](#)

Audit	User	Time (GMT)
AS NEEDED, CLONAZEPAM 0.5MG THREE TIMES A DAY AS NEEDED, HYDROXYZINE HCL 50MG EVERY 6 HOURS AS NEEDED, PRAZOSIN 2 MG DAILY AT BEDTIME, QUETIAPINE 300MG DAILY AT BEDTIME, QUETIAPINE 25 MG DAILY, AND TRAZODONE 100MG AT BEDTIME AS NEEDED.' reason for change: Data Entry Error		
User entered 'This is a 21 year old female that presented with a complaint of "personal plea for insanity." Subject was involuntarily admitted to hospital on 29OCT2020 for mood dysregulation and behavioral disturbances. The subject's involuntary admission ended on 05 November 2020, as the Subject agreed to stay in the hospital for medication adjustment and stabilization. This subject has a past medical history consisting of post traumatic stress disorder, generalized anxiety disorder, dissociative disorder, alcohol abuse, and cannabis abuse. She was recently hospitalized 26OCT2020 to 27OCT2020 for anxiety disorder. Pertinent labs include positive for cannabinoids per urine drug screen. During this stay she showed signs of dissociation, delusion, paranoia, feelings of anxiety, fair sleep, and fair appetite. She denied feelings of suicide or homicidal ideation. She was compliant with medications throughout stay. She attended multiple psycho-spiritual education groups to help learn coping skills. She was given a primary diagnosis of Severe Episode of Recurrent Major Depressive Disorder. Also given a diagnosis of Dissociative disorder related to PTSD. She was discharged on 10NOV2020 after significant improvement and in stable condition. Discharge medications given include bupropion hcl ER 150mg daily, chlorpromazine 100mg every 4 hours as needed, clonazepam 0.5mg three times a day as needed, hydroxyzine hcl 50mg every 6 hours as needed, prazosin 2 mg daily at bedtime, quetiapine 300mg daily at bedtime, quetiapine 25 mg daily, and trazodone 100mg at bedtime as needed.'	Lyly Dang (b) (4)	14 Nov 2020 01:15:36

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	14 Nov 2020 01:15:36

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Nov 2020 01:15:36

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:55:19

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Nov 2020 01:15:36

US3812059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:55:19

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Dissociative disorders, HLT: Dissociative states, PT: Dissociative disorder, LLT: Dissociative disorder - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Nov 2020 01:17:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Nov 2020 01:17:34
Data point term sent to Coder	System	21 Nov 2020 01:15:44
DataPoint Un-verified.	Anya Penly (b) (4) (b) (4)	21 Nov 2020 00:40:48
Coding entries removed.	Anya Penly (b) (4) (b) (4)	21 Nov 2020 00:40:48
User entered 'DISSOCIATive DISORDER' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	21 Nov 2020 00:40:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	18 Nov 2020 21:30:31
User coded data point as SOC: Psychiatric disorders, HLGT: Dissociative disorders, HLT: Dissociative states, PT: Dissociation, LLT: Dissociation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:51:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:51:44
Data point term sent to Coder	System	14 Nov 2020 01:26:10
User entered 'Dissociation Disorder'	Lyly Dang (b) (4) (b) (4) (b) (4)	14 Nov 2020 01:25:29

US3812059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:55:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered 'Yes (Y)'	Lyly Dang (b) (4)	14 Nov 2020 01:25:29

US3812059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:55:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered 'No (N)'	Lyly Dang (b) (4)	14 Nov 2020 01:25:29

US3812059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:55:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered 'No (N)'	Lyly Dang (b) (4)	14 Nov 2020 01:25:29

US3812059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered '29 Oct 2020'	Lyly Dang (b) (4)	14 Nov 2020 01:25:29

US3812059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered empty.	Lyly Dang (b) (4)	14 Nov 2020 01:25:29

US3812059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:55:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 01:25:29

US3812059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:55:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered 'No (N)'	Lyly Dang (b) (4)	14 Nov 2020 01:25:29

US3812059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:55:19

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered '10 Nov 2020'	Lyly Dang (b) (4)	14 Nov 2020 01:25:29

US3812059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:55:19

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered empty.	Lyly Dang (b) (4)	14 Nov 2020 01:25:29

US3812059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:55:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 01:25:29

US3812059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:55:19

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered 'Grade 4 (Grade 4)'	Lyly Dang (b) (4)	14 Nov 2020 01:25:29

US3812059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:55:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	(b) (4), (b) (6)	22 Nov 2020 14:06:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered with 'Reviewed with PI. Not serious' (Site from System).	Lyly Dang (b) (4)	14 Nov 2020 01:26:07
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	14 Nov 2020 01:25:29
User entered 'No (N)'	Lyly Dang (b) (4)	14 Nov 2020 01:25:29

US3812059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:55:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered '0'	Lyly Dang (b) (4)	14 Nov 2020 01:25:29

US3812059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:55:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered '0'	Lyly Dang (b) (4)	14 Nov 2020 01:25:29

US3812059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:55:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered '0'	Lyly Dang (b) (4)	14 Nov 2020 01:25:29

US3812059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:55:19

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered empty.	Lyly Dang (b) (4)	14 Nov 2020 01:25:29

US3812059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:55:19

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered empty.	Lyly Dang (b) (4)	14 Nov 2020 01:25:29

US3812059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:55:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered empty.	Lyly Dang (b) (4)	14 Nov 2020 01:25:29

US3812059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:55:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered empty.	Lyly Dang (b) (4)	14 Nov 2020 01:25:29

US3812059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:55:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered '0'	Lyly Dang (b) (4)	14 Nov 2020 01:25:29

US3812059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:55:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered '0'	Lyly Dang (b) (4)	14 Nov 2020 01:25:29

US3812059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:55:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered '0'	Lyly Dang (b) (4)	14 Nov 2020 01:25:29

US3812059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:55:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Nov 2020 01:26:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Nov 2020 01:26:18
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Lyly Dang (b) (4)	14 Nov 2020 01:26:18
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Nov 2020 01:25:29
User entered empty.	Lyly Dang (b) (4)	14 Nov 2020 01:25:29

US3812059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:55:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Nov 2020 01:26:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Nov 2020 01:26:18
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Lyly Dang (b) (4)	14 Nov 2020 01:26:18
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Nov 2020 01:25:29
User entered empty.	Lyly Dang (b) (4)	14 Nov 2020 01:25:29

US3812059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:55:19

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Nov 2020 01:26:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Nov 2020 01:26:18
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Lyly Dang (b) (4)	14 Nov 2020 01:26:18
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Nov 2020 01:25:29
User entered empty.	Lyly Dang (b) (4)	14 Nov 2020 01:25:29

US3812059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:55:19

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered '0'	Lyly Dang (b) (4)	14 Nov 2020 01:25:29

US3812059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:55:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered '1'	Lyly Dang (b) (4)	14 Nov 2020 01:25:29

US3812059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:55:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered '0'	Lyly Dang (b) (4)	14 Nov 2020 01:25:29

US3812059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:55:19

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Lyly Dang (b) (4)	14 Nov 2020 01:25:29

US3812059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:55:19

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered empty.	Lyly Dang (b) (4)	14 Nov 2020 01:25:29

US3812059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:55:19

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
User entered empty.	Lyly Dang (b) (4)	14 Nov 2020 01:25:29

US3812059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:55:19

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	14 Nov 2020 01:25:29

US3812059

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:55:19

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Nov 2020 01:25:29

US3812059

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:55:19

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 15:15:48
User entered 'USA-US111-2020-mRNA-1273-P301000013'	System	21 Nov 2020 15:15:12
User entered 'New'	(b) (4), (b) (6)	21 Nov 2020 15:15:12

US3812059

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:55:19

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Major depression, LLT: Major depressive disorder, recurrent episode - version MedDRA\\23.0.	Coder Import (b) (4)	20 Nov 2020 02:07:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	20 Nov 2020 02:07:51
Data point term sent to Coder	System	20 Nov 2020 02:06:53
User entered 'Severe Episode of Recurrent Major Depressive Disorder'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

US3812059

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:55:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

US3812059

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:55:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Lyly Dang (b) (4) [REDACTED] [REDACTED]	20 Nov 2020 02:06:29

US3812059

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:55:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

US3812059

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '18 Nov 2020'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

US3812059

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

US3812059

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:55:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 02:06:29

US3812059

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:55:19

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

US3812059

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:55:19

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

US3812059

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered empty.	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

US3812059

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:55:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 02:06:29

US3812059

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:55:19

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 4 (Grade 4)'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

US3812059

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:55:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

US3812059

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:55:19

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

US3812059

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:55:19

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

US3812059

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:55:19

[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)	22 Nov 2020 15:19:04
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'hospital admission date of 18 nov 2020 is noted. ' (Site from System).	Lyly Dang (b) (4)	20 Nov 2020 02:07:08
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	20 Nov 2020 02:06:29
User entered '1'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

US3812059

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:55:19

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Nov 2020'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

US3812059

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:55:19

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

US3812059

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:55:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

US3812059

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:55:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

US3812059

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:55:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

US3812059

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:55:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

US3812059

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:55:19

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

US3812059

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:55:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

US3812059

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:55:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

US3812059

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:55:19

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

US3812059

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:55:19

[None](#)

Audit	User	Time (GMT)
User entered '0'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

US3812059

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:55:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

US3812059

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:55:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

US3812059

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:55:19

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

US3812059

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:55:19

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

US3812059

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:55:19

[Narrative](#)

Audit	User	Time (GMT)
User entered 'This subject is a 21-year-old female who was recently discharged on 10 November 2020 with diagnosis of "Severe Episode of Recurrent Major Depressive Disorder." Per the subject's mother, the subject has been receiving "virtual" outpatient therapy 3 days/week since last Friday (Nov 13, 2020). The outpatient clinic advised the subject's mother that inpatient therapy would be more suitable for the subject at this time. The subject was readmitted for "Severe Episode of Recurrent Major Depressive Disorder" on 18 Nov 2020. No additional information is available. Medical records will be requested.'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

US3812059

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:55:19

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 02:06:29

US3812059

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:55:19

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 02:06:29

US3812059

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:55:19

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Nov 2020 02:06:29

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:55:19

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:20:24
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	07 Aug 2020 14:00:49

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:19

Name of Medication

Audit	User	Time (GMT)
User closed query 'Medical records from SAE indicate the following con meds were given in the hospital: Nicotine lozenge, Clonazepam .5 mg TID, Chlorpromazine 50 mg Q4H/PRN, Acetaminophen 650 mg Q4H/PRN, Mylanta 30 ml Q6H/PRN, Promethazine 25 mg Q4H/PRN, Cepacol lozenge Q2H/PRN, trazadone 100 mg PRN, Benztropine 1 mg tablet Q12H, Benztropine injection 1 mg Q2H. Please review and add as necessary.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 22:41:55
Query 'Medical records from SAE indicate the following con meds were given in the hospital: Nicotine lozenge, Clonazepam .5 mg TID, Chlorpromazine 50 mg Q4H/PRN, Acetaminophen 650 mg Q4H/PRN, Mylanta 30 ml Q6H/PRN, Promethazine 25 mg Q4H/PRN, Cepacol lozenge Q2H/PRN, trazadone 100 mg PRN, Benztropine 1 mg tablet Q12H, Benztropine injection 1 mg Q2H. Please review and add as necessary.' answered with 'Reviewed conmeds from hospitalization 10/29/2020 to 11/10/2020. Nicotine lozenge recorded in EDC. Clonazepam already recorded but updated frequency, chlorpromazine already recorded but updated frequency, trazadone recorded but updated frequency. As for the following, they were ordered however they were never dispensed to the subject therefore not a concomitant medication: Acetaminophen 650 mg Q4H/PRN, Mylanta 30 ml Q6H/PRN, Promethazine 25 mg Q4H/PRN, Cepacol lozenge Q2H/PRN, Benztropine 1 mg tablet Q12H, Benztropine injection 1 mg Q2H' (Site from CRA).	Anya Penly (b) (4) (b) (4)	21 Nov 2020 00:27:57
User opened query 'Medical records from SAE indicate the following con meds were given in the hospital: Nicotine lozenge, Clonazepam .5 mg TID, Chlorpromazine 50 mg Q4H/PRN, Acetaminophen 650 mg Q4H/PRN, Mylanta 30 ml Q6H/PRN, Promethazine 25 mg Q4H/PRN, Cepacol lozenge Q2H/PRN, trazadone 100 mg PRN, Benztropine 1 mg tablet Q12H, Benztropine injection 1 mg Q2H. Please review and add as necessary.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 21:28:04

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAVAGINAL CONTRACEPTIVES, PRODUCT: ETHINYLESTRADIOL;ETONOGESTREL, PRODUCTSYNONYM: NUVARING - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 16:08:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 16:08:18
Data point term sent to Coder	System	07 Aug 2020 14:03:15
User entered 'NUVARING'	Heather Cherniawski (b) (4)	07 Aug 2020 14:02:47

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Query 'Per CDM: Please check and review the data provided as per Indication this medication was given as Prevention.' answered with 'updated' (Site from DM).	Lyly Dang (b) (4)	24 Nov 2020 20:14:29
DataPoint Un-verified.	Lyly Dang (b) (4)	24 Nov 2020 20:13:57
User entered 'Yes (Y)' reason for change: Data Entry Error	Lyly Dang (b) (4)	24 Nov 2020 20:13:57
User opened query 'Per CDM: Please check and review the data provided as per Indication this medication was given as Prevention.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 10:01:40
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'No (N)'	Heather Cherniawski (b) (4)	07 Aug 2020 14:02:47

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'PREGNANCY PREVENTION/ BIRTH CONTROL'	Heather Cherniawski (b) (4)	07 Aug 2020 14:02:47

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered '.135'	Heather Cherniawski (b) (4)	07 Aug 2020 14:02:47

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'mg (mg)'	Heather Cherniawski (b) (4)	07 Aug 2020 14:02:47

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 14:02:47

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'once daily (QD)'	Heather Cherniawski (b) (4)	07 Aug 2020 14:02:47

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 14:02:47

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'Vaginal (VAGINAL)'	Heather Cherniawski (b) (4)	07 Aug 2020 14:02:47

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 14:02:47

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User closed 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).	(b) (4), (b) (6)	10 Aug 2020 19:58:04
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.' answered with 'DM ERROR' (Site from System).	Anya Penly (b) (4)	08 Aug 2020 17:20:06
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).	(b) (4)	
User entered 'UN UNK 2020'	System	07 Aug 2020 14:02:47
	Heather Cherniawski (b) (4)	07 Aug 2020 14:02:47

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered '0'	Heather Cherniawski (b) (4)	07 Aug 2020 14:02:47

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	07 Aug 2020 14:02:47

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 14:02:47

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Aug 2020 17:20:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Aug 2020 17:20:13
User entered 'No (N)' reason for change: Data Entry Error	Anya Penly (b) (4)	08 Aug 2020 17:20:13
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 14:02:47
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 14:02:47

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 14:02:47

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 14:02:47

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Aug 2020 14:02:47

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:19

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: PROSTAGLANDIN ANALOGUES, PRODUCT: TRAVOPROST, PRODUCTSYNONYM: TRAVATAN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 16:16:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 16:16:21
Data point term sent to Coder Coding entries removed.	System Angie Kean (b) (4) (b) (4)	03 Nov 2020 16:16:09 03 Nov 2020 16:15:45
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: PROSTAGLANDIN ANALOGUES, PRODUCT: TRAVOPROST, PRODUCTSYNONYM: TRAVATAN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 14:12:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 14:12:12
Data point term sent to Coder Coding entries removed.	System Heather Cherniawski (b) (4)	07 Aug 2020 14:11:26 07 Aug 2020 14:11:09
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: PROSTAGLANDIN ANALOGUES, PRODUCT: TRAVOPROST, PRODUCTSYNONYM: TRAVATAN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 14:05:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 14:05:17
Data point term sent to Coder User entered 'TRAVATAN'	System Heather Cherniawski (b) (4)	07 Aug 2020 14:04:18 07 Aug 2020 14:04:11

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'No (N)'	Heather Cherniawski (b) (4)	07 Aug 2020 14:04:11

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'GLAUCOMA'	Heather Cherniawski (b) (4)	07 Aug 2020 14:04:11

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered '.05'	Heather Cherniawski (b) (4)	07 Aug 2020 14:04:11

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'mL (mL)'	Heather Cherniawski (b) (4)	07 Aug 2020 14:04:11

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 14:04:11

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'once daily (QD)'	Heather Cherniawski (b) (4)	07 Aug 2020 14:04:11

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 14:04:11

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:14:40
User closed query 'Please confirm with source intraocular or drop. Please confirm and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 02:14:37
Query 'Please confirm with source intraocular or drop. Please confirm and update accordingly. ' answered with 'UPDATED' (Site from CRA).	Angie Kean (b) (4)	03 Nov 2020 16:15:50
DataPoint Un-verified.	(b) (4)	03 Nov 2020 16:15:45
User entered 'Other (OTHER)' reason for change:	Angie Kean (b) (4)	03 Nov 2020 16:15:45
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User opened query 'Please confirm with source intraocular or drop. Please confirm and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	02 Nov 2020 16:34:25
User entered 'Intraocular (INTRAOCULAR)' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	07 Aug 2020 14:11:09
User entered 'Other (OTHER)'	Heather Cherniawski (b) (4)	07 Aug 2020 14:04:11

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:14:43
DataPoint Un-verified.	Angie Kean (b) (4)	03 Nov 2020 16:15:45
User entered 'DROP' reason for change: Data Entry Error	(b) (4)	03 Nov 2020 16:15:45
DataPoint Verified.	Angie Kean (b) (4)	03 Nov 2020 16:15:45
DataPoint Verified.	(b) (4)	02 Nov 2020 16:44:24
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty; reason for change Data Entry Error	Heather Cherniawski	07 Aug 2020 14:11:09
User entered 'DROP'	(b) (4)	07 Aug 2020 14:11:09
	Heather Cherniawski	07 Aug 2020 14:04:11
	(b) (4)	07 Aug 2020 14:04:11

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
DataPoint Un-verified.	Karen Knapp (b) (4)	10 Nov 2020 18:15:57
User entered '01 May 2018' reason for change: Per Query Resolution	Karen Knapp (b) (4)	10 Nov 2020 18:15:57
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User closed 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).	(b) (4), (b) (6)	10 Aug 2020 19:59:17
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.' answered with 'DM ERROR' (Site from System).	Anya Penly (b) (4)	08 Aug 2020 17:20:24
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	07 Aug 2020 14:11:09
User closed query 'Start date is missing and Start date System completely unknown is not checked. Please provide.' (Site from System).	System	07 Aug 2020 14:11:09
User entered '1 May 2018' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	07 Aug 2020 14:11:09
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	07 Aug 2020 14:04:11
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 14:04:11

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered '0'	Heather Cherniawski (b) (4)	07 Aug 2020 14:04:11

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
DataPoint Un-verified.	Angie Kean (b) (4)	14 Nov 2020 01:41:59
User entered 'No (N)' reason for change: New Information	Angie Kean (b) (4)	14 Nov 2020 01:41:59
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	07 Aug 2020 14:04:11

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
DataPoint Un-verified.	Angie Kean (b) (4)	14 Nov 2020 01:41:59
User entered '30 Oct 2020' reason for change: New Information	Angie Kean (b) (4)	14 Nov 2020 01:41:59
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 14:04:11

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Aug 2020 17:20:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Aug 2020 17:20:29
User entered 'No (N)' reason for change: Data Entry Error	Anya Penly (b) (4)	08 Aug 2020 17:20:29
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 14:04:11
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 14:04:11

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 14:04:11

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 14:04:11

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Aug 2020 14:04:11

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:55:19

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: BETA BLOCKING AGENTS, PRODUCT: DORZOLAMIDE HYDROCHLORIDE;TIMOLOL MALEATE, PRODUCTSYNONYM: COSOPT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 16:31:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 16:31:21
Data point term sent to Coder Coding entries removed.	System Angie Kean (b) (4) (b) (4)	03 Nov 2020 16:16:09 03 Nov 2020 16:16:04
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: BETA BLOCKING AGENTS, PRODUCT: DORZOLAMIDE HYDROCHLORIDE;TIMOLOL MALEATE, PRODUCTSYNONYM: COSOPT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 14:08:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 14:08:10
Data point term sent to Coder User entered 'COSOPT'	System Heather Cherniawski (b) (4)	07 Aug 2020 14:07:21 07 Aug 2020 14:06:37

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:55:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'No (N)'	Heather Cherniawski (b) (4)	07 Aug 2020 14:06:37

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:55:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'GLAUCOMA'	Heather Cherniawski (b) (4)	07 Aug 2020 14:06:37

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:55:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered '.05'	Heather Cherniawski (b) (4)	07 Aug 2020 14:06:37

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:55:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'mL (mL)'	Heather Cherniawski (b) (4)	07 Aug 2020 14:06:37

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:55:19

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 14:06:37

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:55:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'twice daily (BID)'	Heather Cherniawski (b) (4)	07 Aug 2020 14:06:37

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:55:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 14:06:37

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:55:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:15:26
User closed query 'Please confirm with source intraocular or drop. Please confirm and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 02:15:24
Query 'Please confirm with source intraocular or drop. Please confirm and update accordingly. ' answered with 'UPDATED' (Site from CRA).	Angie Kean (b) (4)	03 Nov 2020 16:16:09
DataPoint Un-verified.	(b) (4)	03 Nov 2020 16:16:04
User entered 'Other (OTHER)' reason for change:	Angie Kean (b) (4)	03 Nov 2020 16:16:04
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User opened query 'Please confirm with source intraocular or drop. Please confirm and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	02 Nov 2020 16:35:10
User entered 'Intraocular (INTRAOCULAR)'	Heather Cherniawski (b) (4)	07 Aug 2020 14:06:37

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:55:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:15:28
DataPoint Un-verified.	Angie Kean (b) (4)	03 Nov 2020 16:16:04
User entered 'DROP' reason for change: Data Entry Error	(b) (4)	03 Nov 2020 16:16:04
DataPoint Verified.	Angie Kean (b) (4)	03 Nov 2020 16:16:04
DataPoint Verified.	(b) (4)	02 Nov 2020 16:44:24
User entered empty.	(b) (4), (b) (6)	
	Heather Cherniawski	07 Aug 2020 14:06:37
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:55:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
DataPoint Un-verified.	Karen Knapp (b) (4)	10 Nov 2020 18:16:13
User entered '01 May 2018' reason for change: Per Query Resolution	(b) (4)	
DataPoint Verified.	Karen Knapp (b) (4)	10 Nov 2020 18:16:13
	(b) (4)	
	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User closed 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).	(b) (4), (b) (6)	10 Aug 2020 19:59:26
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.' answered with 'DM ERROR' (Site from System).	Anya Penly (b) (4)	08 Aug 2020 17:20:35
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).	(b) (4)	
User entered '1 May 2018'	System	07 Aug 2020 14:06:37
	Heather Cherniawski	07 Aug 2020 14:06:37
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:55:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered '0'	Heather Cherniawski (b) (4)	07 Aug 2020 14:06:37

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:55:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	07 Aug 2020 14:06:37

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:55:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 14:06:37

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:55:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Aug 2020 17:20:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Aug 2020 17:20:40
User entered 'No (N)' reason for change: Data Entry Error	Anya Penly (b) (4)	08 Aug 2020 17:20:40
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 14:06:37
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 14:06:37

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:55:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	07 Aug 2020 14:06:37

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 14:06:37

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Aug 2020 14:06:37

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 14:11:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 14:11:17
Data point term sent to Coder	System	07 Aug 2020 14:10:25
User entered 'SERTRALINE'	Heather Cherniawski (b) (4)	07 Aug 2020 14:09:58

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'No (N)'	Heather Cherniawski (b) (4)	07 Aug 2020 14:09:58

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:19

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication (i.e. ANXIETY) during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 06:47:16
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
Query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication (i.e. ANXIETY) during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' answered with 'UPDATED MEDICAL HISTORY' (Site from DM).	Heather Cherniawski (b) (4)	26 Oct 2020 19:43:53
User opened query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication (i.e. ANXIETY) during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 02:27:40
User entered 'DEPRESSION/ANXIETY'	Heather Cherniawski (b) (4)	07 Aug 2020 14:09:58

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered '100'	Heather Cherniawski (b) (4)	07 Aug 2020 14:09:58

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'mg (mg)'	Heather Cherniawski (b) (4)	07 Aug 2020 14:09:58

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:19

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 14:09:58

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'once daily (QD)'	Heather Cherniawski (b) (4)	07 Aug 2020 14:09:58

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 14:09:58

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'Oral (ORAL)'	Heather Cherniawski (b) (4)	07 Aug 2020 14:09:58

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 14:09:58

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User closed 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).	(b) (4), (b) (6)	10 Aug 2020 19:59:38
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.' answered with 'DM ERROR' (Site from System).	Anya Penly (b) (4)	08 Aug 2020 17:21:05
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	07 Aug 2020 14:09:58
User entered '20 Dec 2019'	Heather Cherniawski (b) (4)	07 Aug 2020 14:09:58

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered '0'	Heather Cherniawski (b) (4)	07 Aug 2020 14:09:58

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	01 Nov 2020 01:19:13
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	07 Aug 2020 14:09:58

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered '24 Oct 2020' reason for change: Data Entry Error	Lyly Dang (b) (4)	01 Nov 2020 01:19:13
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 14:09:58

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Aug 2020 17:20:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Aug 2020 17:20:51
User entered 'No (N)' reason for change: Data Entry Error	Anya Penly (b) (4)	08 Aug 2020 17:20:51
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 14:09:58
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 14:09:58

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 14:09:58

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 14:09:58

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Aug 2020 14:09:58

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:55:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: DIPHENYLMETHANE DERIVATIVES, PRODUCT: HYDROXYZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Nov 2020 01:17:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Nov 2020 01:17:38
Data point term sent to Coder	System	01 Nov 2020 01:16:44
User entered 'Hydroxyzine' reason for change: Data Entry Error	Lyly Dang (b) (4)	01 Nov 2020 01:16:05
Data point term sent to Coder	System	28 Oct 2020 23:16:55
Data point term sent to Coder	System	28 Oct 2020 23:13:51
User entered 'ATARAX'	Lyly Dang (b) (4)	28 Oct 2020 23:13:24

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:55:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'No (N)'	Lyly Dang (b) (4)	28 Oct 2020 23:13:24

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:55:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'Anxiety Disorder' reason for change: Data Entry Error	Lyly Dang (b) (4)	01 Nov 2020 01:16:05
User entered "'Manic episode'"	Lyly Dang (b) (4)	28 Oct 2020 23:13:24

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:55:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered '25' reason for change: Data Entry Error	Lyly Dang (b) (4)	01 Nov 2020 01:16:05
User entered 'unk'	Lyly Dang (b) (4)	28 Oct 2020 23:13:24

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:55:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'mg (mg)' reason for change: Data Entry Error	Lyly Dang (b) (4)	01 Nov 2020 01:16:05
User entered 'Other (OTHER)' reason for change: Data Entry Error	Lyly Dang (b) (4)	28 Oct 2020 23:16:15
User entered 'ug (ug)'	Lyly Dang (b) (4)	28 Oct 2020 23:13:24

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:55:19

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty; reason for change Data Entry Error	Lyly Dang (b) (4)	01 Nov 2020 01:16:05
User entered 'Unknown at this time' reason for change: Data Entry Error	Lyly Dang (b) (4)	28 Oct 2020 23:16:15
User entered empty.	Lyly Dang (b) (4)	28 Oct 2020 23:13:24

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:55:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'once (ONCE)' reason for change: Data Entry Error	Lyly Dang (b) (4)	01 Nov 2020 01:16:05
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 23:16:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 23:16:15
User entered 'unknown (UNKNOWN)' reason for change: Data Entry Error	Lyly Dang (b) (4)	28 Oct 2020 23:16:15
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 23:13:24
User entered empty.	Lyly Dang (b) (4)	28 Oct 2020 23:13:24

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:55:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Lyly Dang (b) (4)	28 Oct 2020 23:13:24

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:55:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 23:16:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 23:16:15
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Lyly Dang (b) (4)	28 Oct 2020 23:16:15
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 23:13:24
User entered empty.	Lyly Dang (b) (4)	28 Oct 2020 23:13:24

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:55:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Lyly Dang (b) (4)	28 Oct 2020 23:13:24

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	28 Oct 2020 23:16:15
User entered '26 Oct 2020' reason for change: Data Entry Error	Lyly Dang (b) (4)	28 Oct 2020 23:16:15
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	28 Oct 2020 23:13:24
User entered empty.	Lyly Dang (b) (4)	28 Oct 2020 23:13:24

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:55:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered '0'	Lyly Dang (b) (4)	28 Oct 2020 23:13:24

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:55:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 23:16:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 23:16:15
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	28 Oct 2020 23:16:15
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 23:13:24
User entered empty.	Lyly Dang (b) (4)	28 Oct 2020 23:13:24

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:55:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered '26 Oct 2020' reason for change: Data Entry Error	Lyly Dang (b) (4)	01 Nov 2020 01:16:05
User entered '27 Oct 2020' reason for change: Data Entry Error	Lyly Dang (b) (4)	28 Oct 2020 23:16:15
User entered empty.	Lyly Dang (b) (4)	28 Oct 2020 23:13:24

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:55:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 23:16:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 23:16:15
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	28 Oct 2020 23:16:15
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 23:13:24
User entered empty.	Lyly Dang (b) (4)	28 Oct 2020 23:13:24

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:55:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 23:13:24

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 23:13:24

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 23:13:24

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN NICOTINE DEPENDENCE, PRODUCT: NICOTINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 22:44:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	30 Oct 2020 22:44:03
Data point term sent to Coder Coding entries removed.	System	30 Oct 2020 22:43:32
	Angie Kean (b) (4)	30 Oct 2020 22:42:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN NICOTINE DEPENDENCE, PRODUCT: NICOTINE - version WHODrug-Global-B3\\202003.	(b) (4)	
	Coder Import (b) (4)	29 Oct 2020 20:12:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	29 Oct 2020 20:12:32
Data point term sent to Coder User entered 'Nicotine patch'	System	28 Oct 2020 23:17:56
	Lyly Dang (b) (4)	28 Oct 2020 23:17:13

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 23:17:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 23:17:49
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	28 Oct 2020 23:17:49
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 23:17:13
User entered empty.	Lyly Dang (b) (4)	28 Oct 2020 23:17:13

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'NICOTINE ADDICTION' reason for change: Data Entry Error	Angie Kean (b) (4)	30 Oct 2020 22:42:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	28 Oct 2020 23:17:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 23:17:49
User entered 'smoking cessation' reason for change: Data Entry Error	Lyly Dang (b) (4)	28 Oct 2020 23:17:49
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 23:17:13
User entered empty.	Lyly Dang (b) (4)	28 Oct 2020 23:17:13

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered '14' reason for change: Data Entry Error	Angie Kean (b) (4)	30 Oct 2020 22:42:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	28 Oct 2020 23:17:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 23:17:49
User entered 'unknown' reason for change: Data Entry Error	Lyly Dang (b) (4)	28 Oct 2020 23:17:49
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 23:17:13
User entered empty.	Lyly Dang (b) (4)	28 Oct 2020 23:17:13

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	30 Oct 2020 22:42:55
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	30 Oct 2020 22:42:47
User entered 'mg (mg)' reason for change: Data Entry Error	Angie Kean (b) (4)	30 Oct 2020 22:42:47
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 23:17:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 23:17:49
User entered 'Other (OTHER)' reason for change: Data Entry Error	Lyly Dang (b) (4)	28 Oct 2020 23:17:49
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 23:17:13
User entered empty.	Lyly Dang (b) (4)	28 Oct 2020 23:17:13

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:19

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty; reason for change Data Entry Error	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:42:55
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	28 Oct 2020 23:17:57
User entered 'Unknown' reason for change: Data Entry Error	Lyly Dang (b) (4) 	28 Oct 2020 23:17:57
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	28 Oct 2020 23:17:49
User entered empty.	Lyly Dang (b) (4) 	28 Oct 2020 23:17:13

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'once (ONCE)' reason for change: Data Entry Error	Angie Kean (b) (4)	30 Oct 2020 22:42:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 23:17:49
User entered 'unknown (UNKNOWN)' reason for change: Data Entry Error	System	28 Oct 2020 23:17:49
User opened query 'Data is required. Please complete.' (Site from System).	Lyly Dang (b) (4)	28 Oct 2020 23:17:49
User entered empty.	(b) (4)	
	System	28 Oct 2020 23:17:13
	Lyly Dang (b) (4)	28 Oct 2020 23:17:13

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Lyly Dang (b) (4)	28 Oct 2020 23:17:13

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 23:17:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 23:17:49
User entered 'Transdermal (TRANSDERMAL)' reason for change: Data Entry Error	Lyly Dang (b) (4)	28 Oct 2020 23:17:49
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 23:17:13
User entered empty.	Lyly Dang (b) (4)	28 Oct 2020 23:17:13

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Lyly Dang (b) (4)	28 Oct 2020 23:17:13

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered '27 Oct 2020' reason for change: Data Entry Error	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:42:07
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	28 Oct 2020 23:17:49
User entered '26 Oct 2020' reason for change: Data Entry Error	Lyly Dang (b) (4) 	28 Oct 2020 23:17:49
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	28 Oct 2020 23:17:13
User entered empty.	Lyly Dang (b) (4) 	28 Oct 2020 23:17:13

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered '0'	Lyly Dang (b) (4)	28 Oct 2020 23:17:13

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'Yes (Y)' reason for change: Data Entry Error	Angie Kean (b) (4)	30 Oct 2020 22:42:07
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	28 Oct 2020 23:17:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 23:17:49
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	28 Oct 2020 23:17:49
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 23:17:13
User entered empty.	Lyly Dang (b) (4)	28 Oct 2020 23:17:13

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty; reason for change Data Entry Error	Angie Kean (b) (4) (b) (4)	30 Oct 2020 22:42:07
User entered '27 Oct 2020' reason for change: Data Entry Error	Lyly Dang (b) (4)	28 Oct 2020 23:17:49
User entered empty.	Lyly Dang (b) (4)	28 Oct 2020 23:17:13

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 23:17:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 23:17:49
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	28 Oct 2020 23:17:49
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 23:17:13
User entered empty.	Lyly Dang (b) (4)	28 Oct 2020 23:17:13

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 23:17:13

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 23:17:13

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 23:17:13

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:55:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN NICOTINE DEPENDENCE, PRODUCT: NICOTINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 03:25:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 03:25:45
Data point term sent to Coder	System	01 Nov 2020 01:18:45
User entered 'Nicotine gum'	Lyly Dang (b) (4) (b) (4) (b) (4)	01 Nov 2020 01:18:30

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:55:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'No (N)'	Lyly Dang (b) (4)	01 Nov 2020 01:18:30

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:55:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'Nicotine addiction'	Lyly Dang (b) (4)	01 Nov 2020 01:18:30

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:55:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered '2'	Lyly Dang (b) (4)	01 Nov 2020 01:18:30

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:55:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'mg (mg)'	Lyly Dang (b) (4)	01 Nov 2020 01:18:30

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:55:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Lyly Dang (b) (4)	01 Nov 2020 01:18:30

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:55:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'as needed (PRN)'	Lyly Dang (b) (4)	01 Nov 2020 01:18:30

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:55:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Lyly Dang (b) (4)	01 Nov 2020 01:18:30

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:55:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'Oral (ORAL)'	Lyly Dang (b) (4)	01 Nov 2020 01:18:30

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:55:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Lyly Dang (b) (4)	01 Nov 2020 01:18:30

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered '27 Oct 2020'	Lyly Dang (b) (4)	01 Nov 2020 01:18:30

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:55:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered '0'	Lyly Dang (b) (4)	01 Nov 2020 01:18:30

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:55:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'Yes (Y)'	Lyly Dang (b) (4)	01 Nov 2020 01:18:30

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:55:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Lyly Dang (b) (4)	01 Nov 2020 01:18:30

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:55:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'No (N)'	Lyly Dang (b) (4)	01 Nov 2020 01:18:30

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:55:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Nov 2020 01:18:30

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Nov 2020 01:18:30

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Nov 2020 01:18:30

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:55:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 03:27:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 03:27:46
Data point term sent to Coder	System	01 Nov 2020 01:20:45
User entered 'Sertraline'	Lyly Dang (b) (4) (b) (4) (b) (4)	01 Nov 2020 01:20:44

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:55:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'No (N)'	Lyly Dang (b) (4)	01 Nov 2020 01:20:44

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:55:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'Depression/anxiety'	Lyly Dang (b) (4)	01 Nov 2020 01:20:44

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:55:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered '150'	Lyly Dang (b) (4)	01 Nov 2020 01:20:44

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:55:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'mg (mg)'	Lyly Dang (b) (4)	01 Nov 2020 01:20:44

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:55:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Lyly Dang (b) (4)	01 Nov 2020 01:20:44

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:55:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'once daily (QD)'	Lyly Dang (b) (4)	01 Nov 2020 01:20:44

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:55:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Lyly Dang (b) (4)	01 Nov 2020 01:20:44

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:55:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'Oral (ORAL)'	Lyly Dang (b) (4)	01 Nov 2020 01:20:44

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:55:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Lyly Dang (b) (4)	01 Nov 2020 01:20:44

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered '24 Oct 2020'	Lyly Dang (b) (4)	01 Nov 2020 01:20:44

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:55:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered '0'	Lyly Dang (b) (4)	01 Nov 2020 01:20:44

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:55:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'No (N)'	Lyly Dang (b) (4)	01 Nov 2020 01:20:44

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:55:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered '26 Oct 2020'	Lyly Dang (b) (4)	01 Nov 2020 01:20:44

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:55:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'No (N)'	Lyly Dang (b) (4)	01 Nov 2020 01:20:44

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:55:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Nov 2020 01:20:44

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Nov 2020 01:20:44

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Nov 2020 01:20:44

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:55:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: SYMPATHOMIMETICS IN GLAUCOMA THERAPY, PRODUCT: BRIMONIDINE TARTRATE, PRODUCTSYNONYM: ALPHAGAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 01:23:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 01:23:43
Data point term sent to Coder	System	01 Nov 2020 01:22:46
User entered 'Alphagan'	Lyly Dang (b) (4) (b) (4)	01 Nov 2020 01:22:24

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:55:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'No (N)'	Lyly Dang (b) (4)	01 Nov 2020 01:22:24

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:55:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'Glaucoma'	Lyly Dang (b) (4)	01 Nov 2020 01:22:24

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:55:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered '0.05'	Lyly Dang (b) (4)	01 Nov 2020 01:22:24

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:55:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'Other (OTHER)'	Lyly Dang (b) (4)	01 Nov 2020 01:22:24

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:55:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'percent'	Lyly Dang (b) (4)	01 Nov 2020 01:22:24

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:55:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'as needed (PRN)'	Lyly Dang (b) (4)	01 Nov 2020 01:22:24

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:55:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Lyly Dang (b) (4)	01 Nov 2020 01:22:24

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:55:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'Intraocular (INTRAOCULAR)'	Lyly Dang (b) (4)	01 Nov 2020 01:22:24

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:55:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Lyly Dang (b) (4)	01 Nov 2020 01:22:24

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered '24 Aug 2020'	Lyly Dang (b) (4)	01 Nov 2020 01:22:24

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:55:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered '0'	Lyly Dang (b) (4)	01 Nov 2020 01:22:24

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:55:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
DataPoint Un-verified.	Angie Kean (b) (4)	14 Nov 2020 01:42:38
User entered 'No (N)' reason for change: New Information	Angie Kean (b) (4)	14 Nov 2020 01:42:38
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'Yes (Y)'	Lyly Dang (b) (4)	01 Nov 2020 01:22:24

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:55:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
DataPoint Un-verified.	Angie Kean (b) (4)	14 Nov 2020 01:42:38
User entered '30 Oct 2020' reason for change: New Information	(b) (4)	14 Nov 2020 01:42:38
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Lyly Dang (b) (4)	01 Nov 2020 01:22:24

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:55:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'No (N)'	Lyly Dang (b) (4)	01 Nov 2020 01:22:24

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:55:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Nov 2020 01:22:24

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Nov 2020 01:22:24

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Nov 2020 01:22:24

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:55:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN NICOTINE DEPENDENCE, PRODUCT: BUPROPION - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Nov 2020 03:23:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	01 Nov 2020 03:23:43
Data point term sent to Coder	System	01 Nov 2020 01:24:46
Data point term sent to Coder	System	01 Nov 2020 01:22:46
User entered 'Bupropion XL'	Lyly Dang (b) (4)	01 Nov 2020 01:22:39

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:55:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Nov 2020 01:23:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Nov 2020 01:23:59
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	01 Nov 2020 01:23:59
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Nov 2020 01:22:39
User entered empty.	Lyly Dang (b) (4)	01 Nov 2020 01:22:39

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:55:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Nov 2020 01:23:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Nov 2020 01:23:59
User entered 'Anxiety Disorder' reason for change: Data Entry Error	Lyly Dang (b) (4)	01 Nov 2020 01:23:59
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Nov 2020 01:22:39
User entered empty.	Lyly Dang (b) (4)	01 Nov 2020 01:22:39

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:55:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Nov 2020 01:23:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Nov 2020 01:23:59
User entered '150' reason for change: Data Entry Error	Lyly Dang (b) (4)	01 Nov 2020 01:23:59
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Nov 2020 01:22:39
User entered empty.	Lyly Dang (b) (4)	01 Nov 2020 01:22:39

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:55:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Nov 2020 01:23:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Nov 2020 01:23:59
User entered 'mg (mg)' reason for change: Data Entry Error	Lyly Dang (b) (4)	01 Nov 2020 01:23:59
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Nov 2020 01:22:39
User entered empty.	Lyly Dang (b) (4)	01 Nov 2020 01:22:39

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:55:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Lyly Dang (b) (4)	01 Nov 2020 01:22:39

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:55:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Nov 2020 01:23:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Nov 2020 01:23:59
User entered 'once daily (QD)' reason for change: Data Entry Error	Lyly Dang (b) (4)	01 Nov 2020 01:23:59
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Nov 2020 01:22:39
User entered empty.	Lyly Dang (b) (4)	01 Nov 2020 01:22:39

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:55:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Lyly Dang (b) (4)	01 Nov 2020 01:22:39

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:55:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Nov 2020 01:23:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Nov 2020 01:23:59
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Lyly Dang (b) (4)	01 Nov 2020 01:23:59
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Nov 2020 01:22:39
User entered empty.	Lyly Dang (b) (4)	01 Nov 2020 01:22:39

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:55:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Lyly Dang (b) (4)	01 Nov 2020 01:22:39

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:55:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	01 Nov 2020 01:23:59
User entered '27 Oct 2020' reason for change: Data Entry Error	Lyly Dang (b) (4)	01 Nov 2020 01:23:59
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	01 Nov 2020 01:22:39
User entered empty.	Lyly Dang (b) (4)	01 Nov 2020 01:22:39

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:55:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered '0'	Lyly Dang (b) (4)	01 Nov 2020 01:22:39

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:55:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Nov 2020 01:23:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Nov 2020 01:23:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Lyly Dang (b) (4)	01 Nov 2020 01:23:59
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Nov 2020 01:22:39
User entered empty.	Lyly Dang (b) (4)	01 Nov 2020 01:22:39

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:55:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Lyly Dang (b) (4)	01 Nov 2020 01:22:39

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:55:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Nov 2020 01:23:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Nov 2020 01:23:59
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	01 Nov 2020 01:23:59
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Nov 2020 01:22:39
User entered empty.	Lyly Dang (b) (4)	01 Nov 2020 01:22:39

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:55:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Nov 2020 01:23:59
User entered empty.	System	01 Nov 2020 01:22:39

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Nov 2020 01:23:59
User entered empty.	System	01 Nov 2020 01:22:39

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Nov 2020 01:23:59
User entered empty.	System	01 Nov 2020 01:22:39

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:55:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 03:25:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 03:25:45
Data point term sent to Coder	System	01 Nov 2020 01:25:47
User entered 'Motrin'	Lyly Dang (b) (4) (b) (4) (b) (4)	01 Nov 2020 01:25:41

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:55:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'No (N)'	Lyly Dang (b) (4)	01 Nov 2020 01:25:41

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:55:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'sore throat, mylagia, headache'	Lyly Dang (b) (4)	01 Nov 2020 01:25:41

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:55:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered '400'	Lyly Dang (b) (4)	01 Nov 2020 01:25:41

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:55:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'mg (mg)'	Lyly Dang (b) (4)	01 Nov 2020 01:25:41

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:55:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Lyly Dang (b) (4)	01 Nov 2020 01:25:41

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:55:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'once daily (QD)'	Lyly Dang (b) (4)	01 Nov 2020 01:25:41

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:55:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Lyly Dang (b) (4)	01 Nov 2020 01:25:41

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:55:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'Oral (ORAL)'	Lyly Dang (b) (4)	01 Nov 2020 01:25:41

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:55:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Lyly Dang (b) (4)	01 Nov 2020 01:25:41

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered '08 Oct 2020'	Lyly Dang (b) (4)	01 Nov 2020 01:25:41

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:55:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered '0'	Lyly Dang (b) (4)	01 Nov 2020 01:25:41

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:55:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'No (N)'	Lyly Dang (b) (4)	01 Nov 2020 01:25:41

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:55:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered '13 Oct 2020'	Lyly Dang (b) (4)	01 Nov 2020 01:25:41

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:55:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'Yes (Y)' reason for change: Data Entry Error	Lyly Dang (b) (4)	01 Nov 2020 01:25:47
User entered 'No (N)'	Lyly Dang (b) (4)	01 Nov 2020 01:25:41

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:55:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Nov 2020 01:25:41

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Nov 2020 01:25:41

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Nov 2020 01:25:41

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:55:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 03:52:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 03:52:39
Data point term sent to Coder	System	14 Nov 2020 01:33:13
User entered 'Bupropion ER'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:32:56

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:55:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:32:56

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:55:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Major Depressive Disorder'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:32:56

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:55:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '150'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:32:56

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:55:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'mg (mg)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:32:56

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:55:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:32:56

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:55:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'once (ONCE)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:32:56

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:55:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:32:56

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:55:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Oral (ORAL)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:32:56

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:55:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:32:56

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '31 Oct 2020'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:32:56

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:55:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '0'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:32:56

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:55:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:32:56

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:55:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:32:56

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:55:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:32:56

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:55:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 01:32:56

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 01:32:56

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 01:32:56

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:55:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: PHENOTHIAZINES WITH ALIPHATIC SIDE-CHAIN, PRODUCT: CHLORPROMAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:53:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:53:45
Data point term sent to Coder	System	14 Nov 2020 01:35:14
User entered 'Chlopromazine'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:34:28

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:55:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:34:28

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:55:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Major Depressive Disorder'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:34:28

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:55:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '100'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:34:28

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:55:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'mg (mg)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:34:28

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:55:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:34:28

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:55:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Anya Penly (b) (4)	21 Nov 2020 00:05:49
User entered 'other (OTHER)' reason for change:	(b) (4)	
Data Entry Error	Anya Penly (b) (4)	21 Nov 2020 00:05:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'as needed (PRN)'	Angie Kean (b) (4)	14 Nov 2020 01:34:28
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:55:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Anya Penly (b) (4)	21 Nov 2020 00:05:49
	(b) (4)	
User entered 'Q4 hours PRN' reason for change:	Anya Penly (b) (4)	21 Nov 2020 00:05:49
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4)	14 Nov 2020 01:34:28
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:55:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Oral (ORAL)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:34:28

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:55:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:34:28

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '06 Nov 2020'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:34:28

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:55:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '0'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:34:28

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:55:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:34:28

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:55:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:34:28

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:55:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:34:28

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:55:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 01:34:28

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 01:34:28

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 01:34:28

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:55:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CLONAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:53:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:53:44
Data point term sent to Coder	System	14 Nov 2020 01:35:16
User entered 'Clonazepam'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:35:07

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:55:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:35:07

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:55:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Major Depressive Disorder'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:35:07

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:55:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '0.5'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:35:07

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:55:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'mg (mg)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:35:07

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:55:19

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:35:07

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:55:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Anya Penly (b) (4)	21 Nov 2020 00:04:25
User entered 'other (OTHER)' reason for change:	(b) (4)	
Data Entry Error	Anya Penly (b) (4)	21 Nov 2020 00:04:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'as needed (PRN)'	Angie Kean (b) (4)	14 Nov 2020 01:35:07
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:55:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Anya Penly (b) (4) (b) (4)	21 Nov 2020 00:04:25
User entered 'TID PRN' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	21 Nov 2020 00:04:25
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:35:07

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:55:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Oral (ORAL)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:35:07

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:55:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:35:07

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '30 Oct 2020'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:35:07

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:55:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '0'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:35:07

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:55:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:35:07

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:55:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:35:07

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:55:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:35:07

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:55:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 01:35:07

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 01:35:07

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 01:35:07

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:55:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: DIPHENYLMETHANE DERIVATIVES, PRODUCT: HYDROXYZINE HYDROCHLORIDE, PRODUCTSYNONYM: HYDROXYZINE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:46:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:46:44
Data point term sent to Coder	System	14 Nov 2020 01:36:16
User entered 'Hydroxyzine hcl'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:35:44

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:55:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:35:44

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:55:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Major Depressive Disorder'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:35:44

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:55:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '50'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:35:44

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:55:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'mg (mg)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:35:44

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:55:19

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:35:44

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:55:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'as needed (PRN)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:35:44

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:55:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:35:44

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:55:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Topical (TOPICAL)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:35:44

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:55:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:35:44

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '31 Oct 2020'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:35:44

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:55:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '0'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:35:44

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:55:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:35:44

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:55:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:35:44

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:55:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:35:44

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:55:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 01:35:44

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 01:35:44

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 01:35:44

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:55:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ANTIADRENERGIC AGENTS, PERIPHERALLY ACTING, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: PRAZOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:16:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:16:42
Data point term sent to Coder	System	14 Nov 2020 01:37:17
User entered 'Prazosin'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:36:34

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:55:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:36:34

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:55:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Major Depressive Disorder'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:36:34

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:55:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '2'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:36:34

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:55:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'mg (mg)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:36:34

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:55:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:36:34

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:55:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'once daily (QD)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:36:34

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:55:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:36:34

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:55:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Oral (ORAL)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:36:34

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:55:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:36:34

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '31 Oct 2020'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:36:34

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:55:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '0'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:36:34

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:55:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:36:34

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:55:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:36:34

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:55:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:36:34

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:55:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Nov 2020 01:36:34

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Nov 2020 01:36:34

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Nov 2020 01:36:34

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:55:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: QUETIAPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:15:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:15:43
Data point term sent to Coder	System	14 Nov 2020 01:38:19
User entered 'Quetiapine'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:37:32

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:55:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:37:32

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:55:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Major Depressive Disorder'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:37:32

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:55:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '300'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:37:32

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:55:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'mg (mg)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:37:32

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:55:19

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:37:32

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:55:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'other (OTHER)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:37:32

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:55:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'QHS'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:37:32

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:55:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Oral (ORAL)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:37:32

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:55:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:37:32

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '31 Oct 2020'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:37:32

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:55:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '0'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:37:32

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:55:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:37:32

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:55:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:37:32

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:55:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:37:32

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:55:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 01:37:32

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 01:37:32

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 01:37:32

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:55:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: QUETIAPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:15:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:15:43
Data point term sent to Coder	System	14 Nov 2020 01:38:19
User entered 'Quetiapine'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:38:01

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:55:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:38:01

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:55:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Major Depressive Disorder'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:38:01

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:55:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '25'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:38:01

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:55:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'mg (mg)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:38:01

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:55:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:38:01

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:55:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'once daily (QD)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:38:01

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:55:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:38:01

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:55:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Oral (ORAL)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:38:01

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:55:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:38:01

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '03 Nov 2020'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:38:01

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:55:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '0'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:38:01

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:55:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:38:01

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:55:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:38:01

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:55:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:38:01

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:55:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Nov 2020 01:38:01

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Nov 2020 01:38:01

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Nov 2020 01:38:01

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:55:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:10:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:10:41
Data point term sent to Coder	System	14 Nov 2020 01:39:20
User entered 'Trazodone'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:38:37

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:55:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:38:37

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:55:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Major Depressive Disorder'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:38:37

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:55:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '100'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:38:37

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:55:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'mg (mg)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:38:37

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:55:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:38:37

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:55:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'as needed (PRN)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:38:37

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:55:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:38:37

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:55:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Oral (ORAL)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:38:37

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:55:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:38:37

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '30 Oct 2020'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:38:37

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:55:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '0'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:38:37

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:55:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:38:37

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:55:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:38:37

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:55:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:38:37

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:55:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 01:38:37

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 01:38:37

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 01:38:37

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:55:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: PROSTAGLANDIN ANALOGUES, PRODUCT: LATANOPROST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 01:40:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 01:40:37
Data point term sent to Coder	System	14 Nov 2020 01:40:20
User entered 'Latanoprost'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:40:13

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:55:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:40:13

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:55:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Glaucoma'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:40:13

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:55:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '0.005'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:40:13

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:55:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'g (g)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:40:13

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:55:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:40:13

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:55:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'once daily (QD)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:40:13

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:55:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:40:13

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:55:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Intraocular (INTRAOCULAR)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:40:13

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:55:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:40:13

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '31 Oct 2020'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:40:13

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:55:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '0'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:40:13

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:55:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:40:13

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:55:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:40:13

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:55:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:40:13

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:55:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Nov 2020 01:40:13

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Nov 2020 01:40:13

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Nov 2020 01:40:13

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:55:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DIPHENHYDRAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:51:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:51:44
Data point term sent to Coder	System	14 Nov 2020 01:41:20
User entered 'Diphenhydramine'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:41:03

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:55:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:41:03

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:55:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Major Depressive Disorder'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:41:03

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:55:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '50'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:41:03

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:55:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'mg (mg)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:41:03

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:55:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:41:03

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:55:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'once (ONCE)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:41:03

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:55:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:41:03

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:55:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Intravenous (INTRAVENOUS)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:41:03

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:55:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:41:03

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '30 Oct 2020'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:41:03

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:55:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '0'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:41:03

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:55:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:41:03

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:55:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '30 Oct 2020'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:41:03

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:55:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:41:03

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:55:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 01:41:03

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 01:41:03

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 01:41:03

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:55:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: BETA BLOCKING AGENTS, PRODUCT: DORZOLAMIDE;TIMOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:50:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:50:45
Data point term sent to Coder	System	14 Nov 2020 01:46:21
User entered 'Dorzolamide-timolol'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:46:10

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:55:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:46:10

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:55:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Glaucoma'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:46:10

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:55:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '22.3/6.8'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:46:10

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:55:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Other (OTHER)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:46:10

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:55:19

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'mg/mL'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:46:10

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:55:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'twice daily (BID)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:46:10

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:55:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:46:10

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:55:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Intraocular (INTRAOCULAR)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:46:10

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:55:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:46:10

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '01 Nov 2020'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:46:10

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:55:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '0'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:46:10

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:55:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:46:10

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:55:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:46:10

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:55:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	14 Nov 2020 01:46:10

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:55:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	14 Nov 2020 01:46:10

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Nov 2020 01:46:10

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Nov 2020 01:46:10

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:55:19

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN NICOTINE DEPENDENCE, PRODUCT: NICOTINE POLACRILEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:04:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:04:59
Data point term sent to Coder	System	21 Nov 2020 00:23:18
User entered 'nicotine polacrilex lozenge'	Any Penly (b) (4) (b) (4)	21 Nov 2020 00:22:36

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:55:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Anya Penly (b) (4) (b) (4)	21 Nov 2020 00:22:36

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:55:19

[Indication](#)

Audit	User	Time (GMT)
User entered 'nicotine addiction'	Anya Penly (b) (4) (b) (4)	21 Nov 2020 00:22:36

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:55:19

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '2'	Anya Penly (b) (4) (b) (4)	21 Nov 2020 00:22:36

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:55:19

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Anya Penly (b) (4) (b) (4)	21 Nov 2020 00:22:36

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:55:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Anya Penly (b) (4) (b) (4)	21 Nov 2020 00:22:36

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:55:19

[Frequency](#)

Audit	User	Time (GMT)
User entered 'other (OTHER)'	Anya Penly (b) (4) (b) (4)	21 Nov 2020 00:22:36

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:55:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered 'Q2hrs PRN'	Anya Penly (b) (4) (b) (4)	21 Nov 2020 00:22:36

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:55:19

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Anya Penly (b) (4) (b) (4)	21 Nov 2020 00:22:36

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:55:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Anya Penly (b) (4) (b) (4)	21 Nov 2020 00:22:36

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:55:19

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

Audit	User	Time (GMT)
User entered '31 Oct 2020'	Anya Penly (b) (4) (b) (4)	21 Nov 2020 00:22:36

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:55:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Anya Penly (b) (4) (b) (4)	21 Nov 2020 00:22:36

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:55:19

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Anya Penly (b) (4) (b) (4)	21 Nov 2020 00:22:36

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:55:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '8 Nov 2020'	Anya Penly (b) (4) (b) (4)	21 Nov 2020 00:22:36

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:55:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Anya Penly (b) (4) (b) (4)	21 Nov 2020 00:22:36

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:55:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Nov 2020 00:22:36

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Nov 2020 00:22:36

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:55:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Nov 2020 00:22:36

US3812059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:55:19

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	03 Sep 2020 12:36:25

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'USA-US111-2020-MRNA-1273-P301000006'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'Yes (Y)'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'No (N)'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'No (N)'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'Yes (Y)'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'No (N)'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'No (N)'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'No (N)'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'Larkin'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'Wadsworth'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered '711 Old Ballas Rd Suite 105'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'St Louis'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:11:36
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:16:32
User entered empty.	System	16 Nov 2020 16:16:15
User entered 'Missouri'	Anya Penly (b) (4)	12 Nov 2020 15:41:50
	(b) (4)	

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered '63141'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:53:05
User entered 'US'	System	29 Oct 2020 19:43:06

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	16 Nov 2020 16:16:47
User entered '2'	System	02 Nov 2020 15:53:16
User entered '1'	System	29 Oct 2020 19:43:06

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'USA-US111-2020-MRNA-1273-P301000006'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'Yes (Y)'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'No (N)'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'No (N)'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'Yes (Y)'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'No (N)'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'No (N)'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'No (N)'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'Larkin'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'Wadsworth'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered '711 Old Ballas Rd Suite 105'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'St Louis'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:11:36
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:16:32
User entered empty.	System	16 Nov 2020 16:16:15
User entered 'Missouri'	Anya Penly (b) (4)	12 Nov 2020 15:41:50
	(b) (4)	

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered '63141'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:53:05
User entered 'US'	System	29 Oct 2020 19:43:06

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	16 Nov 2020 16:16:47
User entered '2'	System	02 Nov 2020 15:53:16
User entered '1'	System	29 Oct 2020 19:43:06

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:55:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
User entered '29/Oct/2020 19:43'	System	29 Oct 2020 19:43:06

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:55:19

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)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:53:05
User entered '1'	(b) (4), (b) (6)	29 Oct 2020 19:43:06

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'USA-US111-2020-MRNA-1273-P301000006'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'Yes (Y)'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'No (N)'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'No (N)'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'Yes (Y)'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'No (N)'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'No (N)'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'No (N)'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'Larkin'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'Wadsworth'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered '711 Old Ballas Rd Suite 105'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'St Louis'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:11:36
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:16:32
User entered empty.	System	16 Nov 2020 16:16:15
User entered 'Missouri'	Anya Penly (b) (4)	12 Nov 2020 15:41:50
	(b) (4)	

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered '63141'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:53:05
User entered 'US'	System	29 Oct 2020 19:43:06

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	16 Nov 2020 16:16:47
User entered '2'	System	02 Nov 2020 15:53:16
User entered '1'	System	29 Oct 2020 19:43:06

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:55:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
User entered '02/Nov/2020 10:53'	System	02 Nov 2020 15:53:16

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:55:19

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)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:16:32
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
User entered '1'	(b) (4), (b) (6)	02 Nov 2020 15:53:16

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'USA-US111-2020-MRNA-1273-P301000006'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'Yes (Y)'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'No (N)'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'No (N)'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'Yes (Y)'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'No (N)'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'No (N)'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'No (N)'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'Larkin'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'Wadsworth'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered '711 Old Ballas Rd Suite 105'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered 'St Louis'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:11:36
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:16:32
User entered empty.	System	16 Nov 2020 16:16:15
User entered 'Missouri'	Anya Penly (b) (4)	12 Nov 2020 15:41:50
	(b) (4)	

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:42:59
User entered '63141'	System	29 Oct 2020 19:42:49

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:53:05
User entered 'US'	System	29 Oct 2020 19:43:06

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	16 Nov 2020 16:16:47
User entered '2'	System	02 Nov 2020 15:53:16
User entered '1'	System	29 Oct 2020 19:43:06

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:55:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:11:11
User entered '16/Nov/2020 11:16'	System	16 Nov 2020 16:16:47

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:55:19

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)	18 Nov 2020 18:11:14
User entered '1'	(b) (4), (b) (6)	16 Nov 2020 16:16:47

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 15:16:24
User entered 'USA-US111-2020-MRNA-1273-P301000013'	System	21 Nov 2020 15:15:12

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 15:16:24
User entered 'Yes (Y)'	System	21 Nov 2020 15:15:12

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 15:16:24
User entered 'No (N)'	System	21 Nov 2020 15:15:12

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 15:16:24
User entered 'No (N)'	System	21 Nov 2020 15:15:12

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 15:16:24
User entered 'Yes (Y)'	System	21 Nov 2020 15:15:12

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 15:16:24
User entered 'No (N)'	System	21 Nov 2020 15:15:12

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 15:16:24
User entered 'No (N)'	System	21 Nov 2020 15:15:12

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 15:16:24
User entered 'No (N)'	System	21 Nov 2020 15:15:12

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 15:16:24
User entered 'Larkin'	System	21 Nov 2020 15:15:12

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 15:16:24
User entered 'Wadsworth'	System	21 Nov 2020 15:15:12

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 15:16:24
User entered '711 Old Ballas Rd Suite 105'	System	21 Nov 2020 15:15:12

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 15:16:24
User entered 'St Louis'	System	21 Nov 2020 15:15:12

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 15:16:24
User entered '63141'	System	21 Nov 2020 15:15:12

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Investigator Country](#)

Audit	User	Time (GMT)
User entered 'US'	System	21 Nov 2020 15:16:37

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Nov 2020 15:16:37

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 15:16:24
User entered 'USA-US111-2020-MRNA-1273-P301000013'	System	21 Nov 2020 15:15:12

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 15:16:24
User entered 'Yes (Y)'	System	21 Nov 2020 15:15:12

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 15:16:24
User entered 'No (N)'	System	21 Nov 2020 15:15:12

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 15:16:24
User entered 'No (N)'	System	21 Nov 2020 15:15:12

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 15:16:24
User entered 'Yes (Y)'	System	21 Nov 2020 15:15:12

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 15:16:24
User entered 'No (N)'	System	21 Nov 2020 15:15:12

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 15:16:24
User entered 'No (N)'	System	21 Nov 2020 15:15:12

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 15:16:24
User entered 'No (N)'	System	21 Nov 2020 15:15:12

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 15:16:24
User entered 'Larkin'	System	21 Nov 2020 15:15:12

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 15:16:24
User entered 'Wadsworth'	System	21 Nov 2020 15:15:12

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 15:16:24
User entered '711 Old Ballas Rd Suite 105'	System	21 Nov 2020 15:15:12

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 15:16:24
User entered 'St Louis'	System	21 Nov 2020 15:15:12

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 15:16:24
User entered '63141'	System	21 Nov 2020 15:15:12

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[Investigator Country](#)

Audit	User	Time (GMT)
User entered 'US'	System	21 Nov 2020 15:16:37

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Nov 2020 15:16:37

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:55:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '21/Nov/2020 10:16'	System	21 Nov 2020 15:16:37

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:55:19

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)
User entered '1'	(b) (4), (b) (6)	21 Nov 2020 15:16:37