

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

Generated By: KC Joubran

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US3812059

Form: Participant Creation

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

[Participant ID](#)

US3812059

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

US3812059

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 19:35:03

Generated On: 10 Jun 2021 09:51:21

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 20 Feb 2021 19:35:02

Generated On: 10 Jun 2021 09:51:21

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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 20 Feb 2021 19:35:02

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Date of Informed Consent (dd MMM yyyy)	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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 20 Feb 2021 19:35:02

Generated On: 10 Jun 2021 09:51:21

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 20 Feb 2021 19:35:02

Generated On: 10 Jun 2021 09:51:21

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 12 Mar 2021 21:48:24

Generated On: 10 Jun 2021 09:51:21

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)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Mar 2021 21:48:24

Generated On: 10 Jun 2021 09:51:21

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)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Mar 2021 21:48:24

Generated On: 10 Jun 2021 09:51:21

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)

Data signed: (b) (4) 12 Mar 2021 21:48:24

Generated On: 10 Jun 2021 09:51:21

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)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 12 Mar 2021 21:48:24

Generated On: 10 Jun 2021 09:51:21

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)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 12 Mar 2021 21:48:24

Generated On: 10 Jun 2021 09:51:21

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 12 Mar 2021 21:48:24

Generated On: 10 Jun 2021 09:51:21

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)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 12 Mar 2021 21:48:24

Generated On: 10 Jun 2021 09:51:21

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)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 12 Mar 2021 21:48:24

Generated On: 10 Jun 2021 09:51:21

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)

Data signed: (b) (4) 12 Mar 2021 21:48:24

Generated On: 10 Jun 2021 09:51:21

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)	_____

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 12 Mar 2021 21:48:24

Generated On: 10 Jun 2021 09:51:21

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)	_____

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 12 Mar 2021 21:48:24

Generated On: 10 Jun 2021 09:51:21

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: Medical History (13)

Data signed: (b) (4) 12 Mar 2021 21:48:24

Generated On: 10 Jun 2021 09:51:21

Condition	RECURRENT MAJOR DEPRESSIVE 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

Data signed: (b) (4) 20 Feb 2021 19:35:03

Generated On: 10 Jun 2021 09:51:21

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)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 19:35:02

Generated On: 10 Jun 2021 09:51:21

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.

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 20 Feb 2021 19:35:02

Generated On: 10 Jun 2021 09:51:21

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

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 20 Feb 2021 19:35:02

Generated On: 10 Jun 2021 09:51:21

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 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) _____

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 20 Feb 2021 19:35:03

Generated On: 10 Jun 2021 09:51:21

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 20 Feb 2021 19:35:03

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	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	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 19:35:03

Generated On: 10 Jun 2021 09:51:21

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

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 20 Feb 2021 19:35:03

Generated On: 10 Jun 2021 09:51:21

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 20 Feb 2021 19:35:03

Generated On: 10 Jun 2021 09:51:21

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 19:35:03

Generated On: 10 Jun 2021 09:51:21

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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 19:35:03

Generated On: 10 Jun 2021 09:51:21

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

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 19:35:03

Generated On: 10 Jun 2021 09:51:21

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 20 Feb 2021 19:35:03

Generated On: 10 Jun 2021 09:51:21

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) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 19:35:03

Generated On: 10 Jun 2021 09:51:21

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 19:35:03

Generated On: 10 Jun 2021 09:51:21

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

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 19:35:03

Generated On: 10 Jun 2021 09:51:21

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

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:35:03

Generated On: 10 Jun 2021 09:51:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:51:21

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐
No ☒

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

PC Time Stamp 06 AUG 2020 11:36

PC Open Date & Time 06 AUG 2020 11:17

PC Close Date & Time 06 AUG 2020 13:47

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °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: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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: 10 Jun 2021 09:51:21

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 10 Jun 2021 09:51:21

TIMEPOINT	DAY 7
Please record - PAIN AT INJECTION SITE.	None ☒
Please select one response below	
Does not interfere with activity	☐
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	☐
Any use of prescription pain reliever or prevents daily activity	☐
Is there any REDNESS AT INJECTION SITE?	Yes ☐
	No ☒
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes ☐
	No ☒
Please record - UNDERARM GLAND SWELLING OR TENDERNESS.	None ☒
Please select one response below	
Does not interfere with activity	☐
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	☐
Any use of prescription pain reliever or prevents daily activity	☐
PC Time Stamp	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: 10 Jun 2021 09:51:21

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:21

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: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some

interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:21

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: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:21

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: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

59 of 3250

EAB) (1725)

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:21

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: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

61 of 3250

EAB) (1725)

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:21

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: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

63 of 3250

EAB) (1725)

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:21

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: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

65 of 3250

EAB) (1725)

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:21

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: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

67 of 3250

EAB) (1725)

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:21

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

Data signed: (b) (4) 20 Feb 2021 19:35:02

Generated On: 10 Jun 2021 09:51:21

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

Data signed: (b) (4) 20 Feb 2021 19:35:02

Generated On: 10 Jun 2021 09:51:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812059

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:34:51

Generated On: 10 Jun 2021 09:51:21

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

Data signed: (b) (4) 20 Feb 2021 19:34:51

Generated On: 10 Jun 2021 09:51:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812059

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:35:02

Generated On: 10 Jun 2021 09:51:21

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

Data signed: (b) (4) 20 Feb 2021 19:35:02

Generated On: 10 Jun 2021 09:51:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812059

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 19:35:03

Generated On: 10 Jun 2021 09:51:21

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)

Data signed: (b) (4) 20 Feb 2021 19:35:03

Generated On: 10 Jun 2021 09:51:21

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)

Data signed: (b) (4) 20 Feb 2021 19:35:03

Generated On: 10 Jun 2021 09:51:21

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

Data signed: (b) (4) 20 Feb 2021 19:35:03

Generated On: 10 Jun 2021 09:51:21

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3812059

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 20 Feb 2021 19:35:03

Generated On: 10 Jun 2021 09:51:21

Was the pregnancy test performed?	Yes ☒
	No ☐
Date of test (dd MMM yyyy)	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

Data signed: (b) (4) 20 Feb 2021 19:35:03

Generated On: 10 Jun 2021 09:51:21

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 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

Data signed: (b) (4) 20 Feb 2021 19:35:03

Generated On: 10 Jun 2021 09:51:21

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	01 SEP 2020
Collection time (00:00-23:59)	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

Data signed: (b) (4) 20 Feb 2021 19:35:03

Generated On: 10 Jun 2021 09:51:21

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

US3812059

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:35:03

Generated On: 10 Jun 2021 09:51:21

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: 10 Jun 2021 09:51:21

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.4 °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: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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: 10 Jun 2021 09:51:21

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: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 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: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 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: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 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: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 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: 10 Jun 2021 09:51:21

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:21

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: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some

interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:21

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: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:21

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: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:21

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: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:21

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: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:21

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: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:21

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: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:21

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

Data signed: (b) (4) 20 Feb 2021 19:35:02

Generated On: 10 Jun 2021 09:51:21

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

Data signed: (b) (4) 20 Feb 2021 19:35:02

Generated On: 10 Jun 2021 09:51:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812059

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:35:02

Generated On: 10 Jun 2021 09:51:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812059

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:35:02

Generated On: 10 Jun 2021 09:51:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812059

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:35:02

Generated On: 10 Jun 2021 09:51:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812059

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:35:02

Generated On: 10 Jun 2021 09:51:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812059

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 19:35:03

Generated On: 10 Jun 2021 09:51:21

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

Data signed: (b) (4) 20 Feb 2021 19:35:03

Generated On: 10 Jun 2021 09:51:21

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

US3812059

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 19:35:03

Generated On: 10 Jun 2021 09:51:21

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3812059

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 19:35:03

Generated On: 10 Jun 2021 09:51:21

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

US3812059

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:35:03

Generated On: 10 Jun 2021 09:51:21

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: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

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: 10 Jun 2021 09:51:21

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please identify below 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
PRODUCTION RELEASE (v12.003 EAB) (1725)	
128 of 3250	

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Patient Cloud Close Date & Time](#)

17 OCT 2020 23:59

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	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: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

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

Date and time of submission

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

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

Date and time of submission

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 10 Jun 2021 09:51:21

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

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

Date and time of submission

Patient Cloud Open Date & Time

21 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: 10 Jun 2021 09:51:21

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 10 Jun 2021 09:51:21

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

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

Date and time of submission

Patient Cloud Open Date & Time

28 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: 10 Jun 2021 09:51:21

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 10 Jun 2021 09:51:21

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

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

Date and time of submission

Patient Cloud Open Date & Time

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: 10 Jun 2021 09:51:21

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 10 Jun 2021 09:51:21

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

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

Date and time of submission

Patient Cloud Open Date & Time

12 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: 10 Jun 2021 09:51:21

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 10 Jun 2021 09:51:21

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

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

Date and time of submission

Patient Cloud Open Date & Time

19 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: 10 Jun 2021 09:51:21

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 10 Jun 2021 09:51:21

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

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

Date and time of submission

Patient Cloud Open Date & Time

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: 10 Jun 2021 09:51:21

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 10 Jun 2021 09:51:21

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

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

Date and time of submission

Patient Cloud Open Date & Time

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: 10 Jun 2021 09:51:21

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 10 Jun 2021 09:51:21

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

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

Date and time of submission

Patient Cloud Open Date & Time

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: 10 Jun 2021 09:51:21

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have 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: 10 Jun 2021 09:51:21

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

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

Date and time of submission

Patient Cloud Open Date & Time

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: 10 Jun 2021 09:51:21

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 10 Jun 2021 09:51:21

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

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

Date and time of submission

Patient Cloud Open Date & Time

23 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: 10 Jun 2021 09:51:21

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 10 Jun 2021 09:51:21

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

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

Date and time of submission

Patient Cloud Open Date & Time

30 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: 10 Jun 2021 09:51:21

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have 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: 10 Jun 2021 09:51:21

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

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

Date and time of submission

Patient Cloud Open Date & Time

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: 10 Jun 2021 09:51:21

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 10 Jun 2021 09:51:21

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

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

Date and time of submission

Patient Cloud Open Date & Time

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: 10 Jun 2021 09:51:21

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 10 Jun 2021 09:51:21

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

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

Date and time of submission

Patient Cloud Open Date & Time

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: 10 Jun 2021 09:51:21

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have 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: 10 Jun 2021 09:51:21

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

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

Date and time of submission

Patient Cloud Open Date & Time

27 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: 10 Jun 2021 09:51:21

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have 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: 10 Jun 2021 09:51:21

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

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

Date and time of submission

Patient Cloud Open Date & Time

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: 10 Jun 2021 09:51:21

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Date and time of submission	15 MAR 2021 09:55:27
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: 10 Jun 2021 09:51:21

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 13:39:09

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3812059

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:51:21

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		15 MAR 2021 09:55:36

US3812059

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:35:02

Generated On: 10 Jun 2021 09:51:21

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

Data signed: (b) (4) 20 Feb 2021 19:35:02

Generated On: 10 Jun 2021 09:51:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812059

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:34:51

Generated On: 10 Jun 2021 09:51:21

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 NOV 2020

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

Comments SUBJECT DID NOT PICK UP
SITE'S CALL OR RETURN SITE'S
If Contact Not Made, please provide Comments CALL

US3812059

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:34:51

Generated On: 10 Jun 2021 09:51:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812059

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:34:51

Generated On: 10 Jun 2021 09:51:21

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 31 DEC 2020

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

Comments SUBJECT DID NOT PICK UP
SITE'S CALL OR RETURN SITE'S
If Contact Not Made, please provide Comments CALL

US3812059

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:34:51

Generated On: 10 Jun 2021 09:51:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812059

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:35:02

Generated On: 10 Jun 2021 09:51:21

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 JAN 2021

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

Comments SUBJECT DID NOT PICK UP
SITE'S CALL OR RETURN SITE'S
If Contact Not Made, please provide Comments CALL

US3812059

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:34:51

Generated On: 10 Jun 2021 09:51:21

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

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)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

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	☐

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	08 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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	☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

	Not Done	☐
Fatigue	None	☐
	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	☐

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

Nasal Congestion

None ☐
Mild ☐
Moderate ☒
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)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

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	☐

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	09 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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	☐

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EAB) (1725)

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

	Not Done	☐
Fatigue	None	☐
	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	☐

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

Nasal Congestion

None ☐
Mild ☐
Moderate ☒
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)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

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	☐

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	10 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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	☐

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EAB) (1725)

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

	Not Done	☐
Fatigue	None	☐
	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	☐

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

Nasal Congestion

None ☐
Mild ☐
Moderate ☒
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 ☐

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

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	☐

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	11 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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	☐

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

	Not Done	☐
Fatigue	None	☐
	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	☐

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

Nasal Congestion

None ☐
Mild ☐
Moderate ☒
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 ☐

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

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	☐

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	12 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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	☐

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

	Not Done	☐
Fatigue	None	☐
	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	☐

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

Nasal Congestion

None ☐
Mild ☐
Moderate ☒
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 ☐

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

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	☐

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	13 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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	☐

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EAB) (1725)

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

	Not Done	☐
Fatigue	None	☒
	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	☐

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
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)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

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	☐

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	14 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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	☐

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

	Not Done	☐
Fatigue	None	☒
	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	☐

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
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)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

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	☐

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	15 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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	☐

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EAB) (1725)

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

	Not Done	☐
Fatigue	None	☒
	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	☐

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
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)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

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	☐

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

	Day 33	☐
	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 ☐

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

	Not Done	☐
Fatigue	None	☒
	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	☐

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
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)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

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	☐

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

	Day 33	☐
	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	☐

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

	Not Done	☐
Fatigue	None	☒
	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	☐

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
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)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

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	☐

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

	Day 33	☐
	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	☐

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

	Not Done	☐
Fatigue	None	☒
	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	☐

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
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)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

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	☐

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

	Day 33	☐
	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	☐

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EAB) (1725)

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

	Not Done	☐
Fatigue	None	☒
	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	☐

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
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

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

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 16 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

CLIA Certified? Yes ☐
No ☐

COVID-19 Positive (CSA Programming Field Only) 0

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3812059

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 20 Feb 2021 19:34:51

Generated On: 10 Jun 2021 09:51:21

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)	

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 19:34:51

Generated On: 10 Jun 2021 09:51:21

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

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 19:34:51

Generated On: 10 Jun 2021 09:51:21

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)	

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 19:34:51

Generated On: 10 Jun 2021 09:51:21

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.

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Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 20 Feb 2021 19:34:51

Generated On: 10 Jun 2021 09:51:21

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

16 OCT 2020

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

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 19:34:51

Generated On: 10 Jun 2021 09:51:21

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 UNBLND_DECIDE

US3812059

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

Form: Unblinding

Data signed: (b) (4) 08 Apr 2021 16:26:03

Generated On: 10 Jun 2021 09:51:21

Date of updated informed consent (dd MMM yyyy)	
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes ☒ No ☐
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ☐ Amendment 6 or later ☒
Date of unblinding (dd MMM yyyy)	23 MAR 2021
Participant randomization assignment	mRNA-1273 ☐ Placebo ☒
Actual Dose 1	mRNA-1273 ☐ Placebo ☒ Not Administered ☐
Actual Dose 2	mRNA-1273 ☐ Placebo ☒ Not Administered ☐
Will participant receive mRNA-1273?	Yes ☐ No ☒
Placebo Only Flag	1
Continuing with mRNA-1273	

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 19:34:51

Generated On: 10 Jun 2021 09:51:21

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 20 Feb 2021 19:34:51

Generated On: 10 Jun 2021 09:51:21

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00 - 23:59)

Collection Date and Time (derived)

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Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

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)

Data signed: (b) (4) 30 Apr 2021 02:45:25

Generated On: 10 Jun 2021 09:51:21

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	

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 02:45:25

Generated On: 10 Jun 2021 09:51:21

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	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)	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 02:45:25

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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	

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Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 02:45:25

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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	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)	_____

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 30 Apr 2021 02:45:25

Generated On: 10 Jun 2021 09:51:21

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 ☐

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Form: Adverse Events (3)

Data signed: (b) (4) 30 Apr 2021 02:45:25

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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	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 30 Apr 2021 02:45:25

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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+

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Form: Adverse Events (3)

Data signed: (b) (4) 30 Apr 2021 02:45:25

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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,
THE SUBJECT WAS
HOSPITALIZED TWO DAYS
LATER AT MERCY
BEHAVIORAL HEALTH FOR
THE SAME DIAGNOSIS.
MEDICAL RECORDS WERE

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Form: Adverse Events (3)

Data signed: (b) (4) 30 Apr 2021 02:45:25

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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.

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 02:45:25

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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 ☐

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Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 02:45:25

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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	
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)	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 02:45:25

Generated On: 10 Jun 2021 09:51:21

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 ☒

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 02:45:25

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	Unknown	☐
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		

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 02:45:25

Generated On: 10 Jun 2021 09:51:21

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

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Form: Adverse Events (5)

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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

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Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 02:45:25

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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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 30 Apr 2021 02:45:25

Generated On: 10 Jun 2021 09:51:21

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

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Form: Adverse Events (6)

Data signed: (b) (4) 30 Apr 2021 02:45:25

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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	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)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 30 Apr 2021 02:45:25

Generated On: 10 Jun 2021 09:51:21

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) 30 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) 18 NOV 2020

Hospital Discharge Date (dd MMM yyyy) 30 NOV 2020

Admitted to ICU? Yes ☐
No ☒

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Form: Adverse Events (7)

Data signed: (b) (4) 30 Apr 2021 02:45:25

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	Unknown	☐
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		True
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		

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 30 Apr 2021 02:45:25

Generated On: 10 Jun 2021 09:51:21

THIS SUBJECT IS A
21-YEAR-OLD FEMALE WHO
WAS HOSPITALIZED ON 18 NOV
2020 WITH AN ADMITTING
DIAGNOSIS OF "MAJOR
DEPRESSIVE DISORDER
RECURRENT." THIS SUBJECT
HAS A PAST MEDICAL HISTORY
OF ANXIETY, DEPRESSION,
POST-TRAUMATIC STRESS
DISORDER, ALCOHOL ABUSE,
AND CANNABIS ABUSE. THE
SUBJECT HAD TWO PRIOR
HOSPITALIZATIONS THIS PAST
YEAR DUE TO HER ANXIETY
DISORDER AND MAJOR
DEPRESSIVE DISORDER. PRIOR
TO THIS HOSPITALIZATION,
THE SUBJECT WAS ATTENDING
AN INTENSIVE OUTPATIENT
BEHAVIORAL HEALTH
PROGRAM 3 DAYS/WEEK UNTIL
IT WAS RECOMMENDED THAT
INPATIENT THERAPY WOULD
BE BETTER SUITED FOR THE
SUBJECT AT THAT TIME.

SUBJECT WAS SUBSEQUENTLY
ADMITTED TO THE HOSPITAL
ON 18 NOV 2020 FOR A
DURATION OF 12 DAYS. PER
MEDICAL RECORDS, THE
SUBJECT RECEIVED
LORAZEPAM 1 MG,
OLANZAPINE 10MG,

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 30 Apr 2021 02:45:25

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QUETIAPINE 400 MG, TRAZADONE 100 MG, AND HYDROXYZINE 50 MG DURING HER HOSPITALIZATION. PERTINENT LABS INCLUDE A NEGATIVE COVID-19 PCR AND POSITIVE URINE DRUG SCREEN FOR CANNABINOIDS. THE SUBJECT WAS DISCHARGED IN STABLE CONDITION ON 30 NOV 2020 WITH THE ORDER TO DISCONTINUE BUPROPION HCL 150 MG DAILY AND TO START LATUDA 40 MG DAILY, CLONAZEPAM 0.5 MG BID, AND BRIMONIDINE 0.2% BID. THE SUBJECT'S FINAL DISCHARGE DIAGNOSIS WAS "SEVERE EPISODE OF RECURRENT MAJOR DEPRESSIVE DISORDER, WITHOUT PSYCHOTIC FEATURES." THE SUBJECT WAS TAKEN TO A SUBSTANCE USE TREATMENT PROGRAM IN ARIZONA THE SAME DAY OF DISCHARGE.

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

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 30 Apr 2021 02:45:25

Generated On: 10 Jun 2021 09:51:21

AEID

Adverse event

COVID-LIKE ILLNESS

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)

08 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)

13 OCT 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

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Form: Adverse Events (8)

Data signed: (b) (4) 30 Apr 2021 02:45:25

Generated On: 10 Jun 2021 09:51:21

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)	_____

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Apr 2021 13:33:25

Generated On: 10 Jun 2021 09:51:21

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)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

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 ☐

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US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

	Intraocular	☐
	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 JUN 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)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

Name of Medication TRAVATAN 0.004%

Prophylaxis Yes ☐
No ☒

Indication GLAUCOMA

Dose per administration 1

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

If dose unit is Other, specify DROP

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☒
If route of administration is Other, specify	OPHTHALMIC	
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)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

Name of Medication COSOPT 6.8MG/ML

Prophylaxis Yes ☐
No ☒

Indication GLAUCOMA

Dose per administration 1

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

If dose unit is Other, specify DROP

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☒
If route of administration is Other, specify		OPHTHALMIC
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)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

	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)	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	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

	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)	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	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

Name of Medication NICOTINE PATCH

Prophylaxis Yes ☐
No ☒

Indication WORSENING 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 ☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

	Intraocular	☐
	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)		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	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

Name of Medication NICOTINE POLAINLEX GUM

Prophylaxis Yes ☐
No ☒

Indication WORSENING 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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

	Intraocular	☐
	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)	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)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

Name of Medication SERTRALINE

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION/ANXIETY

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

	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)	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)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

Name of Medication ALPHAGAN 0.05%

Prophylaxis Yes ☐
No ☒

Indication GLAUCOMA

Dose per administration 1

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

If dose unit is Other, specify DROP

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☒
If route of administration is Other, specify		OPHTHALMIC
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)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

	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)	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)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

Name of Medication MOTRIN

Prophylaxis Yes ☐
No ☒

Indication COVID-LIKE ILLNESS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

	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	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

Name of Medication CHLOPROMAZINE

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

Q4 HOURS PRN

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

	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)	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	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

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

TID PRN

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

	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)		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)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

	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) _____		
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	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

	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) _____		
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	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

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

QHS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

	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) 03 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	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

Name of Medication QUETIAPINE

Prophylaxis Yes ☐
No ☒

Indication MAJOR DEPRESSIVE DISORDER

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

	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)	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	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

	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)		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	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

Name of Medication LATANOPROST 0.005%

Prophylaxis Yes ☐
No ☒

Indication GLAUCOMA

Dose per administration 1

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

If dose unit is Other, specify DROP

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☒
If route of administration is Other, specify		OPHTHALMIC
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 ☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

	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)	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	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

Name of Medication DORZOLAMIDE-TIMOLOL
22.3MG/6.8ML

Prophylaxis Yes ☐
No ☒

Indication GLAUCOMA

Dose per administration 1

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

If dose unit is Other, specify DROP

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☒
If route of administration is Other, specify	OPHTHALMIC	
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	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

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

Q2HRS PRN

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

	Intraocular	☐
	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	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

Name of Medication ALPHAGAN 0.2%

Prophylaxis Yes ☐
No ☒

Indication GLAUCOMA

Dose per administration 1

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

If dose unit is Other, specify DROP

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☒
If route of administration is Other, specify	OPHTHALMIC	
Start date (dd MMM yyyy)	30 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	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

Name of Medication LARASIDONE

Prophylaxis Yes ☐
No ☒

Indication SEVERE EPISODE OF
RECURRENT MAJOR
DEPRESSIVE DISORDER

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

	Intraocular	☐
	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)		30 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 (27)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

Name of Medication CLONAZEPAM

Prophylaxis Yes ☐
No ☒

Indication SEVERE EPISODE OF
RECURRENT 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 Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

	Intraocular	☐
	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)	30 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 (28)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

Name of Medication LORAZEPAM

Prophylaxis Yes ☐
No ☒

Indication SEVERE EPISODE OF
RECURRENT MAJOR
DEPRESSIVE DISORDER

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

	Intraocular	☐
	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)	18 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		18 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 Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

Name of Medication OLANZAPINE

Prophylaxis Yes ☐
No ☒

Indication SEVERE EPISODE OF
RECURRENT MAJOR
DEPRESSIVE DISORDER

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

	Intraocular	☐
	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)	18 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		18 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 Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

Name of Medication QUETIAPINE

Prophylaxis Yes ☐
No ☒

Indication SEVERE EPISODE OF
RECURRENT MAJOR
DEPRESSIVE DISORDER

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

	Intraocular	☐
	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)	18 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		18 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 Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

Name of Medication TRAZODONE

Prophylaxis Yes ☐
No ☒

Indication SEVERE EPISODE OF
RECURRENT 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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

	Intraocular	☐
	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)	19 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		19 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 Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

Name of Medication HYDROXYZINE

Prophylaxis Yes ☐
No ☒

Indication SEVERE EPISODE OF
RECURRENT 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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

	Intraocular	☐
	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)	19 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		19 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 Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

Name of Medication COSOPT
(22.3-6.8MG/ML)

Prophylaxis Yes ☐
No ☒

Indication GLAUCOMA

Dose per administration 1

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

If dose unit is Other, specify DROP (22.3-6.8MG/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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☒
If route of administration is Other, specify	OPHTHALMIC	
Start date (dd MMM yyyy)	18 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	18 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 Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

Name of Medication ALPHAGAN
(0.2%)

Prophylaxis Yes ☐
No ☒

Indication GLAUCOMA

Dose per administration 1

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

If dose unit is Other, specify DROP

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:51:21

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☒
If route of administration is Other, specify	OPHTHALMIC	
Start date (dd MMM yyyy)	19 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	19 NOV 2020	
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 Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 20 Feb 2021 19:34:50

Generated On: 10 Jun 2021 09:51:21

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3812059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 28 Apr 2021 22:16:53

Generated On: 10 Jun 2021 09:51:21

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
26 OCT 2020	URINE DRUG SCREEN	Adverse Event	
UN NOV 2020	SUBSTANCE ABUSE TREATMENT PROGRAM	Adverse Event	

US3812059

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:51:21

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

Data signed: (b) (4) 26 Mar 2021 19:31:31

Generated On: 10 Jun 2021 09:51:21

Date of study discontinuation/completion (dd MMM yyyy) 23 MAR 2021

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

SUBJECT WOULD LIKE TO
RECEIVE THE COVID-19
VACCINE OUTSIDE OF THE
STUDY

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

Data signed: (b) (4) 30 Apr 2021 02:45:28

Generated On: 10 Jun 2021 09:51:21

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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3812059

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

Form: Safety Report Form (1)

Data signed: (b) (4) 30 Apr 2021 02:45:28

Generated On: 10 Jun 2021 09:51:21

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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
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)

Data signed: (b) (4) 30 Apr 2021 02:45:28

Generated On: 10 Jun 2021 09:51:21

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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
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)

Data signed: (b) (4) 30 Apr 2021 02:45:28

Generated On: 10 Jun 2021 09:51:21

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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
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

Data signed: (b) (4) 30 Apr 2021 02:45:28

Generated On: 10 Jun 2021 09:51:21

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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3812059

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

Form: Safety Report Form (1)

Data signed: (b) (4) 30 Apr 2021 02:45:28

Generated On: 10 Jun 2021 09:51:21

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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
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

US3812059

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

Form: Safety Report Form (2)

Data signed: (b) (4) 30 Apr 2021 02:45:28

Generated On: 10 Jun 2021 09:51:21

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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	02/DEC/2020 16:40
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 (3)

Data signed: (b) (4) 30 Apr 2021 02:45:28

Generated On: 10 Jun 2021 09:51:21

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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	16/DEC/2020 14:18
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3812059

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

Form: Safety Report Form (4)

Data signed: (b) (4) 30 Apr 2021 02:45:28

Generated On: 10 Jun 2021 09:51:21

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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	17/DEC/2020 10:05
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 (5)

Data signed: (b) (4) 30 Apr 2021 02:45:28

Generated On: 10 Jun 2021 09:51:21

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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	29/APR/2021 10:59
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: 10 Jun 2021 09:51:21

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'US3812059'	RWS_ENDPOINT	06 Aug 2020 15:29:57
	ENDPOINT (b) (4)	

US3812059

Form: Participant Creation

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:51:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Heather Cherniawski	06 Aug 2020 16:12:38

US3812059

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '06 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 15:29:58

US3812059

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Clinic (Clinic)'	Heather Cherniawski	06 Aug 2020 16:12:38

US3812059

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:51:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered 'SCRN'	System	06 Aug 2020 16:12:38

US3812059

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:21

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered (b) (6) 1999'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 15:29:59

US3812059

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:21

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '20'	Heather Cherniawski (b) (4)	06 Aug 2020 16:13:23

US3812059

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:21

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered 'YEARS'	System	06 Aug 2020 16:13:23

US3812059

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:21

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered '20'	System	06 Aug 2020 16:13:45

US3812059

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:21

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Female (F)'	Heather Cherniawski (b) (4)	06 Aug 2020 16:13:23

US3812059

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:21

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '1'	Heather Cherniawski	06 Aug 2020 16:13:23

US3812059

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:21

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '0'	Heather Cherniawski (b) (4)	06 Aug 2020 16:13:23

US3812059

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:21

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '0'	Heather Cherniawski	06 Aug 2020 16:13:23

US3812059

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:21

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '0'	Heather Cherniawski	06 Aug 2020 16:13:23

US3812059

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:21

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '0'	Heather Cherniawski	06 Aug 2020 16:13:23

US3812059

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:21

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '0'	Heather Cherniawski	06 Aug 2020 16:13:23

US3812059

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:21

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered empty.	Heather Cherniawski	06 Aug 2020 16:13:23

US3812059

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:21

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '0'	Heather Cherniawski (b) (4)	06 Aug 2020 16:13:23

US3812059

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:21

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '0'	Heather Cherniawski	06 Aug 2020 16:13:23

US3812059

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '06 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	10 Nov 2020 17:35:49
User entered '6 Aug 2020'	(b) (4)	
	Heather Cherniawski	06 Aug 2020 16:13:45
	(b) (4)	

US3812059

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered 'Aug 2020'	System	06 Aug 2020 16:13:45

US3812059

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered '2020'	System	06 Aug 2020 16:13:45

US3812059

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:51:21

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Amendment 1 (1)'	Heather Cherniawski	06 Aug 2020 16:13:45

US3812059

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Heather Cherniawski	06 Aug 2020 16:13:45

US3812059

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:51:21

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered empty.	Heather Cherniawski	06 Aug 2020 16:13:45

US3812059

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:51:21

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered empty.	Heather Cherniawski	06 Aug 2020 16:13:45

US3812059

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:51:21

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'No (N)'	Heather Cherniawski	06 Aug 2020 16:13:45

US3812059

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:51:21

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 15:29:58

US3812059

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:51:21

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered '1'	System	06 Aug 2020 16:13:54

US3812059

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Heather Cherniawski	06 Aug 2020 16:13:54

US3812059

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:51:21

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Heather Cherniawski	07 Aug 2020 13:45:53

US3812059

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:51:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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) (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) (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.	Coder Import (b) (4) (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 (b) (4)	26 Oct 2020 19:36:15
Coding entries removed.	Heather Cherniawski (b) (4)	26 Oct 2020 19:36:06
User entered 'LEFT EYE GLAUCOMA' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	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) (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.	Coder Import (b) (4) (b) (4)	07 Aug 2020 13:48:14

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:51:21

[Condition](#)

Audit	User	Time (GMT)
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered (b) (6) 1999'	Heather Cherniawski	07 Aug 2020 13:46:25

US3812059

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '0'	Heather Cherniawski	07 Aug 2020 13:46:25

US3812059

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:51:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Heather Cherniawski	07 Aug 2020 13:46:25

US3812059

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 13:46:25

US3812059

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:51:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '0'	Heather Cherniawski	07 Aug 2020 13:46:25

US3812059

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered (b) (6) 1999'	System	07 Aug 2020 13:46:25

US3812059

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered '1999'	System	07 Aug 2020 13:46:25

US3812059

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered empty.	System	07 Aug 2020 13:46:25

US3812059

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered empty.	System	07 Aug 2020 13:46:25

US3812059

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:51:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User closed query 'Hospital records indicate Dissociative disorder and Borderline Personality Disorder. Please review and reconcile.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:53:16
User closed query 'Condition is listed as "Depression" but con meds give the indication as "Major Depressive Dissorder" Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 18:53:03
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 Dissorder" 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 Dissorder" Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 18:31:04

US3812059

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:51:21

[Condition](#)

Audit	User	Time (GMT)
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.	Coder Import (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 (b) (4)	07 Aug 2020 13:46:41

US3812059

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'UN UNK 2018'	Heather Cherniawski (b) (4)	07 Aug 2020 13:46:41

US3812059

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '0'	Heather Cherniawski	07 Aug 2020 13:46:41

US3812059

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:51:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Heather Cherniawski	07 Aug 2020 13:46:41

US3812059

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered empty.	Heather Cherniawski	07 Aug 2020 13:46:41

US3812059

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:51:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '0'	Heather Cherniawski	07 Aug 2020 13:46:41

US3812059

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered 'Jan 2018'	System	07 Aug 2020 13:46:41

US3812059

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered '2018'	System	07 Aug 2020 13:46:41

US3812059

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered empty.	System	07 Aug 2020 13:46:41

US3812059

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered empty.	System	07 Aug 2020 13:46:41

US3812059

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:51:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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)	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)	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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User closed query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	(b) (4)	08 Aug 2020 16:23:10
User entered (b) (6) 1999' reason for change: New Information	Any 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: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '0'	Heather Cherniawski	07 Aug 2020 13:47:14

US3812059

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:51:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Heather Cherniawski	07 Aug 2020 13:47:14

US3812059

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered empty.	Heather Cherniawski	07 Aug 2020 13:47:14

US3812059

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:51:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '0'	Heather Cherniawski	07 Aug 2020 13:47:14

US3812059

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered '1999'	System	07 Aug 2020 13:47:14

US3812059

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered empty.	System	07 Aug 2020 13:47:14

US3812059

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered empty.	System	07 Aug 2020 13:47:14

US3812059

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:51:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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)	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)	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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'UN UNK 2008'	Heather Cherniawski	07 Aug 2020 13:47:37

US3812059

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '0'	Heather Cherniawski	07 Aug 2020 13:47:37

US3812059

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:51:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Heather Cherniawski	07 Aug 2020 13:47:37

US3812059

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered empty.	Heather Cherniawski	07 Aug 2020 13:47:37

US3812059

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:51:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '0'	Heather Cherniawski	07 Aug 2020 13:47:37

US3812059

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered 'Jan 2008'	System	07 Aug 2020 13:47:37

US3812059

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered '2008'	System	07 Aug 2020 13:47:37

US3812059

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered empty.	System	07 Aug 2020 13:47:37

US3812059

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered empty.	System	07 Aug 2020 13:47:37

US3812059

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:51:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User coded data point as SOC: Social circumstances, HLT: Tobacco use, PT: Electronic cigarette user, LLT: Vapor cigarette smoker - version MedDRA\23.0.	Coder Import (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)	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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'UN UNK 2018'	Heather Cherniawski	07 Aug 2020 13:47:58

US3812059

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '0'	Heather Cherniawski	07 Aug 2020 13:47:58

US3812059

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:51:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Heather Cherniawski	07 Aug 2020 13:47:58

US3812059

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered empty.	Heather Cherniawski	07 Aug 2020 13:47:58

US3812059

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:51:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '0'	Heather Cherniawski	07 Aug 2020 13:47:58

US3812059

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered 'Jan 2018'	System	07 Aug 2020 13:47:58

US3812059

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered '2018'	System	07 Aug 2020 13:47:58

US3812059

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered empty.	System	07 Aug 2020 13:47:58

US3812059

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered empty.	System	07 Aug 2020 13:47:58

US3812059

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:51:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Eye therapeutic procedures NEC, PT: Eye operation, LLT: Eye operation - version MedDRA\23.0.	Coder Import (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)	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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User closed query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	(b) (4)	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

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Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '0'	Heather Cherniawski	07 Aug 2020 13:49:07

US3812059

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:51:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'No (N)'	Heather Cherniawski	07 Aug 2020 13:49:07

US3812059

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'UN UNK 2013'	Heather Cherniawski	07 Aug 2020 13:49:07

US3812059

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:51:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '0'	Heather Cherniawski	07 Aug 2020 13:49:07

US3812059

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered '1999'	System	07 Aug 2020 13:49:07

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Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered 'Jan 2013'	System	07 Aug 2020 13:49:07

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Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered '2013'	System	07 Aug 2020 13:49:07

US3812059

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:51:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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.	Coder Import (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.	Coder Import (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

US3812059

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered empty.	Breanna Galibert (b) (4)	11 Aug 2020 22:30:25

US3812059

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '1'	Breanna Galibert (b) (4)	11 Aug 2020 22:30:25

US3812059

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:51:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	11 Aug 2020 22:30:25

US3812059

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered empty.	Breanna Galibert (b) (4)	11 Aug 2020 22:30:25

US3812059

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:51:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '0'	Breanna Galibert (b) (4)	11 Aug 2020 22:30:25

US3812059

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered empty.	System	11 Aug 2020 22:30:25

US3812059

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered empty.	System	11 Aug 2020 22:30:25

US3812059

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered empty.	System	11 Aug 2020 22:30:25

US3812059

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered empty.	System	11 Aug 2020 22:30:25

US3812059

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:51:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User closed query 'Hospital records indicate GAD. Please reconcile.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:54:04
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, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\23.0.	Coder Import (b) (4) (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.	Coder Import (b) (4) (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 (b) (4)	26 Oct 2020 19:42:48

US3812059

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:51:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '0'	Heather Cherniawski	26 Oct 2020 19:42:48

US3812059

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered 'Jan 2018'	System	26 Oct 2020 19:42:48

US3812059

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered '2018'	System	26 Oct 2020 19:42:48

US3812059

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered empty.	System	26 Oct 2020 19:42:48

US3812059

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered empty.	System	26 Oct 2020 19:42:48

US3812059

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:51:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:24:22
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 01:15:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:51:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:51:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered 'Jan 2020'	System	01 Nov 2020 01:14:40

US3812059

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered '2020'	System	01 Nov 2020 01:14:40

US3812059

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered empty.	System	01 Nov 2020 01:14:40

US3812059

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered empty.	System	01 Nov 2020 01:14:40

US3812059

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:51:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:24:06
User coded data point as SOC: Psychiatric disorders, HLGT: 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.	Coder Import (b) (4)	03 Nov 2020 17:06:21
Data point term sent to Coder	System	03 Nov 2020 17:05:26
User entered 'MARIJUANA ABUSE'	Angie Kean (b) (4)	03 Nov 2020 17:04:58

US3812059

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:24:08
User entered 'UN Feb 2019'	Angie Kean (b) (4)	03 Nov 2020 17:04:58

US3812059

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:24:09
User entered '0'	Angie Kean (b) (4)	03 Nov 2020 17:04:58

US3812059

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:51:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:24:12
User entered 'Yes (Y)'	Angie Kean (b) (4)	03 Nov 2020 17:04:58

US3812059

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:24:13
User entered empty.	Angie Kean (b) (4)	03 Nov 2020 17:04:58

US3812059

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:51:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:24:15
User entered '0'	Angie Kean (b) (4)	03 Nov 2020 17:04:58

US3812059

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered 'Feb 2019'	System	03 Nov 2020 17:04:58

US3812059

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered '2019'	System	03 Nov 2020 17:04:58

US3812059

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered empty.	System	03 Nov 2020 17:04:58

US3812059

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered empty.	System	03 Nov 2020 17:04:58

US3812059

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:51:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User coded data point as SOC: Psychiatric disorders, HLT: 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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'un Jan 2020'	Breanna Galibert (b) (4)	16 Nov 2020 18:55:28

US3812059

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '0'	Breanna Galibert (b) (4)	16 Nov 2020 18:55:28

US3812059

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:51:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	16 Nov 2020 18:55:28

US3812059

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered empty.	Breanna Galibert (b) (4)	16 Nov 2020 18:55:28

US3812059

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:51:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '0'	Breanna Galibert (b) (4)	16 Nov 2020 18:55:28

US3812059

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered 'Jan 2020'	System	16 Nov 2020 18:55:28

US3812059

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered '2020'	System	16 Nov 2020 18:55:28

US3812059

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered empty.	System	16 Nov 2020 18:55:28

US3812059

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered empty.	System	16 Nov 2020 18:55:28

US3812059

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:51:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User coded data point as SOC: Psychiatric disorders, 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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'un Jan 2020'	Breanna Galibert (b) (4)	16 Nov 2020 18:55:52

US3812059

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '0'	Breanna Galibert (b) (4)	16 Nov 2020 18:55:52

US3812059

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:51:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	16 Nov 2020 18:55:52

US3812059

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered empty.	Breanna Galibert (b) (4)	16 Nov 2020 18:55:52

US3812059

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:51:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '0'	Breanna Galibert (b) (4)	16 Nov 2020 18:55:52

US3812059

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered 'Jan 2020'	System	16 Nov 2020 18:55:52

US3812059

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered '2020'	System	16 Nov 2020 18:55:52

US3812059

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered empty.	System	16 Nov 2020 18:55:52

US3812059

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered empty.	System	16 Nov 2020 18:55:52

US3812059

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:51:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	08 Mar 2021 19:30:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Mar 2021 19:30:40
Data point term sent to Coder	System	08 Mar 2021 19:30:18
User entered 'RECURRENT MAJOR DEPRESSIVE DISORDER'	lauren clement (b) (4)	08 Mar 2021 19:29:26

US3812059

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
User entered 'UN Jan 2020'	lauren clement (b) (4)	08 Mar 2021 19:29:26

US3812059

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
User entered '0'	lauren clement (b) (4)	08 Mar 2021 19:29:26

US3812059

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:51:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
User entered 'Yes (Y)'	lauren clement (b) (4)	08 Mar 2021 19:29:26

US3812059

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
User entered empty.	lauren clement (b) (4)	08 Mar 2021 19:29:26

US3812059

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:51:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
User entered '0'	lauren clement (b) (4)	08 Mar 2021 19:29:26

US3812059

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered 'Jan 2020'	System	08 Mar 2021 19:29:26

US3812059

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered '2020'	System	08 Mar 2021 19:29:26

US3812059

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered empty.	System	08 Mar 2021 19:29:26

US3812059

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered empty.	System	08 Mar 2021 19:29:26

US3812059

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Heather Cherniawski	07 Aug 2020 13:49:43

US3812059

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '06 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	10 Nov 2020 17:36:34
User entered '6 Aug 2020'	(b) (4)	
	Heather Cherniawski	07 Aug 2020 13:49:43
	(b) (4)	

US3812059

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '09:30'	Heather Cherniawski	07 Aug 2020 13:49:43

US3812059

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '64.8' in	Heather Cherniawski	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: 10 Jun 2021 09:51:21

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '137' lb	Heather Cherniawski	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: 10 Jun 2021 09:51:21

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
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: 10 Jun 2021 09:51:21

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
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: 10 Jun 2021 09:51:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User closed query 'Per CDM: For combined visit, to be marked as 'ND'. ' (Site from DM).	(b) (4) (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) (b) (4)	25 Aug 2020 15:33:36
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 16:57:39
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: 10 Jun 2021 09:51:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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) (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: 10 Jun 2021 09:51:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User closed query 'Per CDM: For combined visit, to be marked as 'ND'. ' (Site from DM).	(b) (4) (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) (b) (4)	25 Aug 2020 15:33:42
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 16:57:50
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: 10 Jun 2021 09:51:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User closed query 'Per CDM: For combined visit, to be marked as 'ND'. ' (Site from DM).	(b) (4)	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)	25 Aug 2020 15:33:45
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 16:57:56
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: 10 Jun 2021 09:51:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
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: 10 Jun 2021 09:51:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User closed query 'Per CDM: For combined visit, to be marked as 'ND'. ' (Site from DM).	(b) (4) (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) (b) (4)	25 Aug 2020 15:33:48
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 16:58:01
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: 10 Jun 2021 09:51:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
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: 10 Jun 2021 09:51:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User closed query 'Per CDM: For combined visit, to be marked as 'ND'. ' (Site from DM).	(b) (4)	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).	(b) (4), (b) (6)	
	Anya Penly (b) (4)	25 Aug 2020 15:33:51
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Anya Penly (b) (4)	25 Aug 2020 15:33:20
	(b) (4)	
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	07 Aug 2020 13:50:09
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Aug 2020 13:49:43
User entered empty.	Heather Cherniawski	07 Aug 2020 13:49:43
	(b) (4)	

US3812059

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
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: 10 Jun 2021 09:51:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27

US3812059

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27

US3812059

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:51:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Heather Cherniawski	07 Aug 2020 13:50:43

US3812059

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:51:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '06 Aug 2020' reason for change: Data Entry Error	(b) (4)	
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	Maureen Dempsey (b) (4)	10 Nov 2020 17:36:42
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	07 Sep 2020 10:59:13
User entered '6 Aug 2020'	Heather Cherniawski (b) (4)	01 Sep 2020 20:40:06
		07 Aug 2020 13:50:43

US3812059

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:51:21

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '06 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	10 Nov 2020 17:37:10
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	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	07 Aug 2020 13:51:25
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 13:51:15
User entered empty.	Heather Cherniawski	07 Aug 2020 13:51:15
	(b) (4)	

US3812059

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Heather Cherniawski	07 Aug 2020 13:51:15

US3812059

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered empty.	Heather Cherniawski	07 Aug 2020 13:51:15

US3812059

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:51:21

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 13:51:15

US3812059

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered empty.	Heather Cherniawski	07 Aug 2020 13:51:15

US3812059

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:51:21

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '0'	Heather Cherniawski	07 Aug 2020 13:51:15

US3812059

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered empty.	Heather Cherniawski	07 Aug 2020 13:51:15

US3812059

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:51:21

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '0'	Heather Cherniawski	07 Aug 2020 13:51:15

US3812059

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:51:21

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Heather Cherniawski	07 Aug 2020 13:52:57

US3812059

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:51:21

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Urine (URINE)'	Heather Cherniawski	07 Aug 2020 13:52:57

US3812059

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:51:21

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Negative (NEGATIVE)'	Heather Cherniawski	07 Aug 2020 13:52:57

US3812059

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:51:21

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'No (N)'	Heather Cherniawski	07 Aug 2020 13:52:57

US3812059

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:51:21

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered empty.	Heather Cherniawski	07 Aug 2020 13:52:57

US3812059

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:51:21

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 13:52:57

US3812059

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User entered empty.	System	07 Aug 2020 13:52:57

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'No (N)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:53:38

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'No (N)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:53:38

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'No (N)'	Heather Cherniawski	07 Aug 2020 13:53:38

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'No (N)'	Heather Cherniawski	07 Aug 2020 13:53:38

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'No (N)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:53:38

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'No (N)'	Heather Cherniawski	07 Aug 2020 13:53:38

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'No (N)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:53:38

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'No (N)'	Heather Cherniawski	07 Aug 2020 13:53:38

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'No (N)'	Heather Cherniawski	07 Aug 2020 13:53:38

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:53:38

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'No (N)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:53:38

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:21

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'No (N)'	Heather Cherniawski	07 Aug 2020 13:53:38

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:21

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 13:53:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:21

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '0'	Heather Cherniawski	07 Aug 2020 13:53:38

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:21

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '0'	Heather Cherniawski (b) (4)	07 Aug 2020 13:53:38

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '0'	Heather Cherniawski	07 Aug 2020 13:53:38

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '1'	Heather Cherniawski	07 Aug 2020 13:53:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '0'	Heather Cherniawski	07 Aug 2020 13:53:38

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '0'	Heather Cherniawski (b) (4)	07 Aug 2020 13:53:38

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:21

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '0'	Heather Cherniawski	07 Aug 2020 13:53:38

US3812059

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:21

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered empty.	Heather Cherniawski	07 Aug 2020 13:53:38

US3812059

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:51:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Heather Cherniawski	07 Aug 2020 13:54:11

US3812059

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '06 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	10 Nov 2020 17:37:37
User entered '6 Aug 2020'	(b) (4)	
	Heather Cherniawski	07 Aug 2020 13:54:11
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Clinic (Clinic)'	Heather Cherniawski	07 Aug 2020 13:54:11

US3812059

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:51:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User entered 'VISIT1'	System	07 Aug 2020 13:54:11

US3812059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '06 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 15:40:02

US3812059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	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)	06 Aug 2020 15:40:02

US3812059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 15:40:02

US3812059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'No (N)'	Heather Cherniawski	07 Aug 2020 13:56:32

US3812059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'No (N)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:56:32

US3812059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'No (N)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:56:32

US3812059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'No (N)'	Heather Cherniawski (b) (4)	07 Aug 2020 13:56:32

US3812059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:51:21

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'No (N)'	Heather Cherniawski	07 Aug 2020 13:56:32

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:51:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered missing code ND - Not Done.	Heather Cherniawski	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
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: 10 Jun 2021 09:51:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '06 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	10 Nov 2020 17:38:04
User entered '6 Aug 2020'	(b) (4)	
	Heather Cherniawski	07 Aug 2020 13:59:11
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '09:30'	Heather Cherniawski	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
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: 10 Jun 2021 09:51:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User entered 'bpm'	System	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User entered 'breaths/min'	System	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User entered 'mmHg'	System	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '62'	Heather Cherniawski	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User entered 'mmHg'	System	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:51:21

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered missing code ND - Not Done.	Heather Cherniawski	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:51:21

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
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: 10 Jun 2021 09:51:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Heather Cherniawski	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '06 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	10 Nov 2020 17:38:04
User entered '6 Aug 2020'	(b) (4)	
	Heather Cherniawski	07 Aug 2020 13:59:11
	(b) (4)	

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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) (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) (b) (4)	08 Aug 2020 13:56:09
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		07 Aug 2020 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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
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: 10 Jun 2021 09:51:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User entered 'bpm'	System	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User entered 'breaths/min'	System	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '110'	Heather Cherniawski	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User entered 'mmHg'	System	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User entered 'mmHg'	System	07 Aug 2020 13:59:11

US3812059

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:51:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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) (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) (b) (4)	06 Oct 2020 20:53:11
User entered 'No (N)' reason for change: Data Entry Error	Breanna Galibert (b) (4) (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: 10 Jun 2021 09:51:21

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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	07 Aug 2020 14:11:59

US3812059

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:51:21

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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	07 Aug 2020 14:11:59

US3812059

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:51:21

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 14:11:59

US3812059

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:51:21

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered empty.	Heather Cherniawski (b) (4)	07 Aug 2020 14:11:59

US3812059

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:51:21

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User entered empty.	System	07 Aug 2020 14:11:59

US3812059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:51:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Heather Cherniawski	06 Aug 2020 16:35:18

US3812059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:51:21

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered empty.	Heather Cherniawski	06 Aug 2020 16:35:18

US3812059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered empty.	Heather Cherniawski (b) (4)	06 Aug 2020 16:35:18

US3812059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:51:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User entered 'MRNA-1273 OR PLACEBO'	System	06 Aug 2020 16:35:18

US3812059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '06 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	10 Nov 2020 17:38:21
User entered '6 Aug 2020'	(b) (4)	
	Heather Cherniawski	06 Aug 2020 16:35:18
	(b) (4)	

US3812059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '10:57'	Heather Cherniawski	06 Aug 2020 16:35:18

US3812059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Left Arm (LEFT ARM)'	Heather Cherniawski	06 Aug 2020 16:35:18

US3812059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User entered 'ONCE'	System	06 Aug 2020 16:35:18

US3812059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User entered 'INTRAMUSCULAR'	System	06 Aug 2020 16:35:18

US3812059

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Heather Cherniawski	07 Aug 2020 13:59:51

US3812059

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '10:35'	Heather Cherniawski	07 Aug 2020 13:59:51

US3812059

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
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: 10 Jun 2021 09:51:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
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: 10 Jun 2021 09:51:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Heather Cherniawski	07 Aug 2020 14:00:09

US3812059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:51:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '10:38'	Heather Cherniawski	07 Aug 2020 14:00:09

US3812059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
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: 10 Jun 2021 09:51:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
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: 10 Jun 2021 09:51:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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	07 Aug 2020 14:00:13
User entered 'No (N)' reason for change: Data Entry Error	Heather Cherniawski	07 Aug 2020 14:00:13
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	07 Aug 2020 14:00:09
	Heather Cherniawski	07 Aug 2020 14:00:09
	(b) (4)	

US3812059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:51:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User entered empty.	System	07 Aug 2020 14:00:09

US3812059

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	13 Aug 2020 20:09:42

US3812059

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:51:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User entered '1'	System	13 Aug 2020 20:09:42

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'Yes (Y)'	System	06 Aug 2020 16:36:29
	System	06 Aug 2020 16:36:29

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:51:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '98.2'	System	06 Aug 2020 16:36:29
	System	06 Aug 2020 16:36:29

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	06 Aug 2020 16:36:29
	System	06 Aug 2020 16:36:29

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:51:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '06 Aug 2020 11:36'	System	06 Aug 2020 16:36:29
	System	06 Aug 2020 16:36:29

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'Yes (Y)'	System	07 Aug 2020 04:15:50
	System	07 Aug 2020 04:15:50

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:51:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '99.3'	System	07 Aug 2020 04:15:50
	System	07 Aug 2020 04:15:50

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	07 Aug 2020 04:15:50
	System	07 Aug 2020 04:15:50

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:51:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '06 Aug 2020 23:15'	System	07 Aug 2020 04:15:50
	System	07 Aug 2020 04:15:50

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'Yes (Y)'	System	08 Aug 2020 03:32:50
	System	08 Aug 2020 03:32:50

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '98.7'	System	08 Aug 2020 03:32:50
	System	08 Aug 2020 03:32:50

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	08 Aug 2020 03:32:50
	System	08 Aug 2020 03:32:50

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '07 Aug 2020 22:32'	System	08 Aug 2020 03:32:50
	System	08 Aug 2020 03:32:50

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'Yes (Y)'	System	09 Aug 2020 03:26:01
	System	09 Aug 2020 03:26:01

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:51:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '99.0'	System	09 Aug 2020 03:26:01
	System	09 Aug 2020 03:26:01

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	09 Aug 2020 03:26:01
	System	09 Aug 2020 03:26:01

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:51:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '08 Aug 2020 22:25'	System	09 Aug 2020 03:26:01
	System	09 Aug 2020 03:26:01

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'Yes (Y)'	System	09 Aug 2020 23:19:51
	System	09 Aug 2020 23:19:51

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:51:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '98.8'	System	09 Aug 2020 23:19:51
	System	09 Aug 2020 23:19:51

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '99.0'	System	11 Aug 2020 03:26:41
	System	11 Aug 2020 03:26:41

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '10 Aug 2020 22:26'	System	11 Aug 2020 03:26:41
	System	11 Aug 2020 03:26:41

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'Yes (Y)'	System	12 Aug 2020 13:59:08
	System	12 Aug 2020 13:59:08

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:51:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '98.9'	System	12 Aug 2020 13:59:08
	System	12 Aug 2020 13:59:08

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '12 Aug 2020 08:59'	System	12 Aug 2020 13:59:08
	System	12 Aug 2020 13:59:08

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'Yes (Y)'	System	13 Aug 2020 00:57:32
	System	13 Aug 2020 00:57:32

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:51:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '98.6'	System	13 Aug 2020 00:57:32
	System	13 Aug 2020 00:57:32

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	13 Aug 2020 00:57:32
	System	13 Aug 2020 00:57:32

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:51:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '12 Aug 2020 19:57'	System	13 Aug 2020 00:57:32
	System	13 Aug 2020 00:57:32

US3812059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (1)'	System	06 Aug 2020 16:37:23
	System	06 Aug 2020 16:37:23

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	06 Aug 2020 16:37:23
	System	06 Aug 2020 16:37:23

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	06 Aug 2020 16:37:23
	System	06 Aug 2020 16:37:23

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (1)'	System	06 Aug 2020 16:37:23
	System	06 Aug 2020 16:37:23

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '06 Aug 2020 11:37'	System	06 Aug 2020 16:37:23
	System	06 Aug 2020 16:37:23

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	07 Aug 2020 04:10:36
	System	07 Aug 2020 04:10:36

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '06 Aug 2020 23:10'	System	07 Aug 2020 04:10:36
	System	07 Aug 2020 04:10:36

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' 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: 10 Jun 2021 09:51:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	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: 10 Jun 2021 09:51:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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
	System	08 Aug 2020 03:26:31

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (1)'	System	09 Aug 2020 02:57:21
	System	09 Aug 2020 02:57:21

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:51:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	09 Aug 2020 02:57:21
	System	09 Aug 2020 02:57:21

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	09 Aug 2020 02:57:21
	System	09 Aug 2020 02:57:21

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:51:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (1)'	System	09 Aug 2020 02:57:21
	System	09 Aug 2020 02:57:21

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:51:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '08 Aug 2020 21:57'	System	09 Aug 2020 02:57:21
	System	09 Aug 2020 02:57:21

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (1)'	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: 10 Jun 2021 09:51:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	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: 10 Jun 2021 09:51:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (1)'	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: 10 Jun 2021 09:51:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	11 Aug 2020 00:15:16
	System	11 Aug 2020 00:15:16

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '10 Aug 2020 19:15'	System	11 Aug 2020 00:15:16
	System	11 Aug 2020 00:15:16

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (1)'	System	11 Aug 2020 20:06:48
	System	11 Aug 2020 20:06:48

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	11 Aug 2020 20:06:48
	System	11 Aug 2020 20:06:48

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	11 Aug 2020 20:06:48
	System	11 Aug 2020 20:06:48

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (1)'	System	11 Aug 2020 20:06:48
	System	11 Aug 2020 20:06:48

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '11 Aug 2020 15:06'	System	11 Aug 2020 20:06:48
	System	11 Aug 2020 20:06:48

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (1)'	System	13 Aug 2020 00:55:32
	System	13 Aug 2020 00:55:32

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	13 Aug 2020 00:55:32
	System	13 Aug 2020 00:55:32

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	13 Aug 2020 00:55:32
	System	13 Aug 2020 00:55:32

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (1)'	System	13 Aug 2020 00:55:32
	System	13 Aug 2020 00:55:32

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '12 Aug 2020 19:55'	System	13 Aug 2020 00:55:32
	System	13 Aug 2020 00:55:32

US3812059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	06 Aug 2020 16:38:13
	System	06 Aug 2020 16:38:13

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	06 Aug 2020 16:38:13
	System	06 Aug 2020 16:38:13

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	06 Aug 2020 16:38:13
	System	06 Aug 2020 16:38:13

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	06 Aug 2020 16:38:13
	System	06 Aug 2020 16:38:13

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	06 Aug 2020 16:38:13
	System	06 Aug 2020 16:38:13

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	06 Aug 2020 16:38:13
	System	06 Aug 2020 16:38:13

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	06 Aug 2020 16:38:13
	System	06 Aug 2020 16:38:13

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '06 Aug 2020 11:38'	System	06 Aug 2020 16:38:13
	System	06 Aug 2020 16:38:13

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	07 Aug 2020 04:09:23
	System	07 Aug 2020 04:09:23

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	07 Aug 2020 04:09:23
	System	07 Aug 2020 04:09:23

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	07 Aug 2020 04:09:23
	System	07 Aug 2020 04:09:23

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	07 Aug 2020 04:09:23
	System	07 Aug 2020 04:09:23

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	07 Aug 2020 04:09:23
	System	07 Aug 2020 04:09:23

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	07 Aug 2020 04:09:23
	System	07 Aug 2020 04:09:23

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '06 Aug 2020 23:09'	System	07 Aug 2020 04:09:23
	System	07 Aug 2020 04:09:23

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	08 Aug 2020 02:51:02
	System	08 Aug 2020 02:51:02

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	08 Aug 2020 02:51:02
	System	08 Aug 2020 02:51:02

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	08 Aug 2020 02:51:02
	System	08 Aug 2020 02:51:02

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	08 Aug 2020 02:51:02
	System	08 Aug 2020 02:51:02

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	08 Aug 2020 02:51:02
	System	08 Aug 2020 02:51:02

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	08 Aug 2020 02:51:02
	System	08 Aug 2020 02:51:02

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	08 Aug 2020 02:51:02
	System	08 Aug 2020 02:51:02

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '07 Aug 2020 21:51'	System	08 Aug 2020 02:51:02
	System	08 Aug 2020 02:51:02

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	09 Aug 2020 02:57:38
	System	09 Aug 2020 02:57:38

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	09 Aug 2020 02:57:38
	System	09 Aug 2020 02:57:38

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	09 Aug 2020 02:57:38
	System	09 Aug 2020 02:57:38

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	09 Aug 2020 02:57:38
	System	09 Aug 2020 02:57:38

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	09 Aug 2020 02:57:38
	System	09 Aug 2020 02:57:38

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	09 Aug 2020 02:57:38
	System	09 Aug 2020 02:57:38

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	09 Aug 2020 02:57:38
	System	09 Aug 2020 02:57:38

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '08 Aug 2020 21:57'	System	09 Aug 2020 02:57:38
	System	09 Aug 2020 02:57:38

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	09 Aug 2020 22:37:55
	System	09 Aug 2020 22:37:55

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	09 Aug 2020 22:37:55
	System	09 Aug 2020 22:37:55

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	09 Aug 2020 22:37:55
	System	09 Aug 2020 22:37:55

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	09 Aug 2020 22:37:55
	System	09 Aug 2020 22:37:55

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	09 Aug 2020 22:37:55
	System	09 Aug 2020 22:37:55

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	09 Aug 2020 22:37:55
	System	09 Aug 2020 22:37:55

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	09 Aug 2020 22:37:55
	System	09 Aug 2020 22:37:55

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '09 Aug 2020 17:37'	System	09 Aug 2020 22:37:55
	System	09 Aug 2020 22:37:55

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	11 Aug 2020 00:15:30
	System	11 Aug 2020 00:15:30

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	11 Aug 2020 00:15:30
	System	11 Aug 2020 00:15:30

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	11 Aug 2020 00:15:30
	System	11 Aug 2020 00:15:30

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	11 Aug 2020 00:15:30
	System	11 Aug 2020 00:15:30

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	11 Aug 2020 00:15:30
	System	11 Aug 2020 00:15:30

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	11 Aug 2020 00:15:30
	System	11 Aug 2020 00:15:30

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	11 Aug 2020 20:06:31
	System	11 Aug 2020 20:06:31

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	11 Aug 2020 20:06:31
	System	11 Aug 2020 20:06:31

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	11 Aug 2020 20:06:31
	System	11 Aug 2020 20:06:31

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	11 Aug 2020 20:06:31
	System	11 Aug 2020 20:06:31

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	11 Aug 2020 20:06:31
	System	11 Aug 2020 20:06:31

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	11 Aug 2020 20:06:31
	System	11 Aug 2020 20:06:31

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	11 Aug 2020 20:06:31
	System	11 Aug 2020 20:06:31

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '11 Aug 2020 15:06'	System	11 Aug 2020 20:06:31
	System	11 Aug 2020 20:06:31

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	13 Aug 2020 00:55:47
	System	13 Aug 2020 00:55:47

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	13 Aug 2020 00:55:47
	System	13 Aug 2020 00:55:47

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	13 Aug 2020 00:55:47
	System	13 Aug 2020 00:55:47

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	13 Aug 2020 00:55:47
	System	13 Aug 2020 00:55:47

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	13 Aug 2020 00:55:47
	System	13 Aug 2020 00:55:47

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	13 Aug 2020 00:55:47
	System	13 Aug 2020 00:55:47

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	13 Aug 2020 00:55:47
	System	13 Aug 2020 00:55:47

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '12 Aug 2020 19:55'	System	13 Aug 2020 00:55:47
	System	13 Aug 2020 00:55:47

US3812059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	13 Aug 2020 20:10:50

US3812059

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '13 Aug 2020'	Breanna Galibert (b) (4)	13 Aug 2020 20:10:50

US3812059

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered empty.	Breanna Galibert (b) (4)	13 Aug 2020 20:10:50

US3812059

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	25 Aug 2020 22:30:49

US3812059

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User entered '1'	System	25 Aug 2020 22:30:49

US3812059

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	25 Aug 2020 22:31:02

US3812059

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered '21 Aug 2020'	Breanna Galibert (b) (4)	25 Aug 2020 22:31:02

US3812059

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered 'Contact Made (CONTACT MADE)'	Breanna Galibert (b) (4)	25 Aug 2020 22:31:02

US3812059

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered empty.	Breanna Galibert (b) (4)	25 Aug 2020 22:31:02

US3812059

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	31 Aug 2020 17:18:20

US3812059

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User entered '1'	System	31 Aug 2020 17:18:20

US3812059

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	31 Aug 2020 17:18:30

US3812059

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '27 Aug 2020'	Breanna Galibert (b) (4)	31 Aug 2020 17:18:30

US3812059

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Contact Made (CONTACT MADE)'	Breanna Galibert (b) (4)	31 Aug 2020 17:18:30

US3812059

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered empty.	Breanna Galibert (b) (4)	31 Aug 2020 17:18:30

US3812059

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	01 Sep 2020 20:39:57

US3812059

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User entered '1'	System	01 Sep 2020 20:39:57

US3812059

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	01 Sep 2020 20:40:06

US3812059

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:21

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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), (b) (6)	11 Sep 2020 09:14:47
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).	Anya Penly (b) (4)	04 Sep 2020 22:43:37
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	01 Sep 2020 20:40:06
User entered '1 Sep 2020'	Breanna Galibert (b) (4)	01 Sep 2020 20:40:06

US3812059

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4)	01 Sep 2020 20:40:06

US3812059

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User entered 'VISIT2'	System	01 Sep 2020 20:40:06

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
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: 10 Jun 2021 09:51:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Heather Cherniawski	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '01 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	10 Nov 2020 17:40:00
User entered '1 Sep 2020'	(b) (4)	
	Heather Cherniawski	14 Sep 2020 22:07:55
	(b) (4)	

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '14:36'	Heather Cherniawski	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
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: 10 Jun 2021 09:51:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Oral (Oral)'	Heather Cherniawski	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User entered 'bpm'	System	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
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: 10 Jun 2021 09:51:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '100'	Heather Cherniawski	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User entered 'mmHg'	System	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User entered 'mmHg'	System	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
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: 10 Jun 2021 09:51:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '01 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	10 Nov 2020 17:40:00
User entered '1 Sep 2020'	(b) (4)	
	Heather Cherniawski	14 Sep 2020 22:07:55
	(b) (4)	

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
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: 10 Jun 2021 09:51:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User entered 'bpm'	System	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
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: 10 Jun 2021 09:51:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User entered 'mmHg'	System	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User entered 'mmHg'	System	14 Sep 2020 22:07:55

US3812059

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:51:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered empty.	Heather Cherniawski	14 Sep 2020 22:05:14

US3812059

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:51:21

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Heather Cherniawski	14 Sep 2020 22:06:23

US3812059

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:51:21

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '01 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	10 Nov 2020 17:40:12
User entered '1 Sep 2020'	(b) (4)	
	Heather Cherniawski	14 Sep 2020 22:06:23
	(b) (4)	

US3812059

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:51:21

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Urine (URINE)'	Heather Cherniawski	14 Sep 2020 22:06:23

US3812059

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:51:21

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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) (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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User entered empty.	System	14 Sep 2020 22:06:23

US3812059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	01 Sep 2020 20:40:21

US3812059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:21

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered empty.	Breanna Galibert (b) (4)	01 Sep 2020 20:40:21

US3812059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered empty.	Breanna Galibert (b) (4)	01 Sep 2020 20:40:21

US3812059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User entered 'MRNA-1273 OR PLACEBO'	System	01 Sep 2020 20:40:21

US3812059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '01 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	10 Nov 2020 17:40:26
User entered '1 Sep 2020'	(b) (4)	
	Breanna Galibert (b) (4)	01 Sep 2020 20:40:21
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '15:09'	Breanna Galibert (b) (4)	01 Sep 2020 20:40:21

US3812059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Left Arm (LEFT ARM)'	Breanna Galibert (b) (4)	01 Sep 2020 20:40:21

US3812059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User entered 'ONCE'	System	01 Sep 2020 20:40:21

US3812059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User entered 'INTRAMUSCULAR'	System	01 Sep 2020 20:40:21

US3812059

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '01 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	10 Nov 2020 17:40:33
User entered '1 Sep 2020'	(b) (4)	
	Heather Cherniawski	14 Sep 2020 22:05:44
	(b) (4)	

US3812059

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '14:55'	Heather Cherniawski	14 Sep 2020 22:05:44

US3812059

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
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: 10 Jun 2021 09:51:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '01 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	10 Nov 2020 17:40:40
User entered '1 Sep 2020'	(b) (4)	
	Heather Cherniawski	14 Sep 2020 22:05:59
	(b) (4)	

US3812059

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:51:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
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: 10 Jun 2021 09:51:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
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: 10 Jun 2021 09:51:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
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: 10 Jun 2021 09:51:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User entered empty.	System	14 Sep 2020 22:05:59

US3812059

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Karen Knapp (b) (4)	09 Sep 2020 11:56:18

US3812059

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User entered '1'	System	09 Sep 2020 11:56:18

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'Yes (Y)'	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: 10 Jun 2021 09:51:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	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: 10 Jun 2021 09:51:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '01 Sep 2020 15:44'	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: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'Yes (Y)'	System	02 Sep 2020 05:52:53
	System	02 Sep 2020 05:52:53

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:51:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '98.4'	System	02 Sep 2020 05:52:53
	System	02 Sep 2020 05:52:53

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	02 Sep 2020 05:52:53
	System	02 Sep 2020 05:52:53

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:51:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '02 Sep 2020 00:52'	System	02 Sep 2020 05:52:53
	System	02 Sep 2020 05:52:53

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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-a7e8-88b103ffcdcb' User entered 'Yes (Y)'	System	03 Sep 2020 13:58:21
	System	03 Sep 2020 13:58:21

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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-a7e8-88b103ffcdbc' User entered '98.5'	System	03 Sep 2020 13:58:21
	System	03 Sep 2020 13:58:21

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '03 Sep 2020 08:58'	System	03 Sep 2020 13:58:21
	System	03 Sep 2020 13:58:21

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'Yes (Y)'	System	04 Sep 2020 04:51:22
	System	04 Sep 2020 04:51:22

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:51:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '98.5'	System	04 Sep 2020 04:51:22
	System	04 Sep 2020 04:51:22

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	04 Sep 2020 04:51:22
	System	04 Sep 2020 04:51:22

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:51:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '03 Sep 2020 23:51'	System	04 Sep 2020 04:51:22
	System	04 Sep 2020 04:51:22

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'Yes (Y)'	System	05 Sep 2020 14:54:01
	System	05 Sep 2020 14:54:01

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:51:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '98.8'	System	05 Sep 2020 14:54:01
	System	05 Sep 2020 14:54:01

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	05 Sep 2020 14:54:01
	System	05 Sep 2020 14:54:01

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:51:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '05 Sep 2020 09:53'	System	05 Sep 2020 14:54:01
	System	05 Sep 2020 14:54:01

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'Yes (Y)'	System	06 Sep 2020 04:11:33
	System	06 Sep 2020 04:11:33

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:51:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '98.9'	System	06 Sep 2020 04:11:33
	System	06 Sep 2020 04:11:33

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	06 Sep 2020 04:11:33
	System	06 Sep 2020 04:11:33

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:51:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '05 Sep 2020 23:11'	System	06 Sep 2020 04:11:33
	System	06 Sep 2020 04:11:33

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'Yes (Y)'	System	07 Sep 2020 01:50:04
	System	07 Sep 2020 01:50:04

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:51:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '99.3'	System	07 Sep 2020 01:50:04
	System	07 Sep 2020 01:50:04

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	07 Sep 2020 01:50:04
	System	07 Sep 2020 01:50:04

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:51:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '06 Sep 2020 20:49'	System	07 Sep 2020 01:50:04
	System	07 Sep 2020 01:50:04

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'Yes (Y)'	System	08 Sep 2020 04:41:57
	System	08 Sep 2020 04:41:57

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:51:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '99.0'	System	08 Sep 2020 04:41:57
	System	08 Sep 2020 04:41:57

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	08 Sep 2020 04:41:57
	System	08 Sep 2020 04:41:57

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:51:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '07 Sep 2020 23:41'	System	08 Sep 2020 04:41:57
	System	08 Sep 2020 04:41:57

US3812059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (1)'	System	01 Sep 2020 20:44:46
	System	01 Sep 2020 20:44:46

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	01 Sep 2020 20:44:46
	System	01 Sep 2020 20:44:46

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	01 Sep 2020 20:44:46
	System	01 Sep 2020 20:44:46

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (1)'	System	01 Sep 2020 20:44:46
	System	01 Sep 2020 20:44:46

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '01 Sep 2020 15:44'	System	01 Sep 2020 20:44:46
	System	01 Sep 2020 20:44:46

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (1)'	System	02 Sep 2020 05:53:19
	System	02 Sep 2020 05:53:19

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	02 Sep 2020 05:53:19
	System	02 Sep 2020 05:53:19

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	02 Sep 2020 05:53:19
	System	02 Sep 2020 05:53:19

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (1)'	System	02 Sep 2020 05:53:19
	System	02 Sep 2020 05:53:19

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '02 Sep 2020 00:53'	System	02 Sep 2020 05:53:19
	System	02 Sep 2020 05:53:19

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	03 Sep 2020 13:57:46
	System	03 Sep 2020 13:57:46

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:51:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '03 Sep 2020 08:57'	System	03 Sep 2020 13:57:46
	System	03 Sep 2020 13:57:46

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (1)'	System	05 Sep 2020 14:53:38
	System	05 Sep 2020 14:53:38

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:51:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	05 Sep 2020 14:53:38
	System	05 Sep 2020 14:53:38

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	05 Sep 2020 14:53:38
	System	05 Sep 2020 14:53:38

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:51:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (1)'	System	05 Sep 2020 14:53:38
	System	05 Sep 2020 14:53:38

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:51:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '05 Sep 2020 09:53'	System	05 Sep 2020 14:53:38
	System	05 Sep 2020 14:53:38

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (1)'	System	06 Sep 2020 04:11:43
	System	06 Sep 2020 04:11:43

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	06 Sep 2020 04:11:43
	System	06 Sep 2020 04:11:43

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	06 Sep 2020 04:11:43
	System	06 Sep 2020 04:11:43

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (1)'	System	06 Sep 2020 04:11:43
	System	06 Sep 2020 04:11:43

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '05 Sep 2020 23:11'	System	06 Sep 2020 04:11:43
	System	06 Sep 2020 04:11:43

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (1)'	System	07 Sep 2020 01:48:49
	System	07 Sep 2020 01:48:49

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	07 Sep 2020 01:48:49
	System	07 Sep 2020 01:48:49

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	07 Sep 2020 01:48:49
	System	07 Sep 2020 01:48:49

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (1)'	System	07 Sep 2020 01:48:49
	System	07 Sep 2020 01:48:49

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '06 Sep 2020 20:48'	System	07 Sep 2020 01:48:49
	System	07 Sep 2020 01:48:49

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (1)'	System	08 Sep 2020 02:33:43
	System	08 Sep 2020 02:33:43

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	08 Sep 2020 02:33:43
	System	08 Sep 2020 02:33:43

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	08 Sep 2020 02:33:43
	System	08 Sep 2020 02:33:43

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (1)'	System	08 Sep 2020 02:33:43
	System	08 Sep 2020 02:33:43

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '07 Sep 2020 21:33'	System	08 Sep 2020 02:33:43
	System	08 Sep 2020 02:33:43

US3812059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	01 Sep 2020 20:45:03
	System	01 Sep 2020 20:45:03

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	01 Sep 2020 20:45:03
	System	01 Sep 2020 20:45:03

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	01 Sep 2020 20:45:03
	System	01 Sep 2020 20:45:03

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	01 Sep 2020 20:45:03
	System	01 Sep 2020 20:45:03

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	01 Sep 2020 20:45:03
	System	01 Sep 2020 20:45:03

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	01 Sep 2020 20:45:03
	System	01 Sep 2020 20:45:03

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	01 Sep 2020 20:45:03
	System	01 Sep 2020 20:45:03

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '01 Sep 2020 15:44'	System	01 Sep 2020 20:45:03
	System	01 Sep 2020 20:45:03

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	02 Sep 2020 05:53:36
	System	02 Sep 2020 05:53:36

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	02 Sep 2020 05:53:36
	System	02 Sep 2020 05:53:36

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	02 Sep 2020 05:53:36
	System	02 Sep 2020 05:53:36

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	02 Sep 2020 05:53:36
	System	02 Sep 2020 05:53:36

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	02 Sep 2020 05:53:36
	System	02 Sep 2020 05:53:36

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	02 Sep 2020 05:53:36
	System	02 Sep 2020 05:53:36

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '02 Sep 2020 00:53'	System	02 Sep 2020 05:53:36
	System	02 Sep 2020 05:53:36

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	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: 10 Jun 2021 09:51:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	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: 10 Jun 2021 09:51:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	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: 10 Jun 2021 09:51:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	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: 10 Jun 2021 09:51:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	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: 10 Jun 2021 09:51:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	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: 10 Jun 2021 09:51:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	04 Sep 2020 04:50:50
	System	04 Sep 2020 04:50:50

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	04 Sep 2020 04:50:50
	System	04 Sep 2020 04:50:50

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	04 Sep 2020 04:50:50
	System	04 Sep 2020 04:50:50

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	04 Sep 2020 04:50:50
	System	04 Sep 2020 04:50:50

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	04 Sep 2020 04:50:50
	System	04 Sep 2020 04:50:50

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	04 Sep 2020 04:50:50
	System	04 Sep 2020 04:50:50

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	04 Sep 2020 04:50:50
	System	04 Sep 2020 04:50:50

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '03 Sep 2020 23:50'	System	04 Sep 2020 04:50:50
	System	04 Sep 2020 04:50:50

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	05 Sep 2020 14:53:11
	System	05 Sep 2020 14:53:11

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	05 Sep 2020 14:53:11
	System	05 Sep 2020 14:53:11

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	05 Sep 2020 14:53:11
	System	05 Sep 2020 14:53:11

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	05 Sep 2020 14:53:11
	System	05 Sep 2020 14:53:11

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	05 Sep 2020 14:53:11
	System	05 Sep 2020 14:53:11

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	05 Sep 2020 14:53:11
	System	05 Sep 2020 14:53:11

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	05 Sep 2020 14:53:11
	System	05 Sep 2020 14:53:11

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '05 Sep 2020 09:53'	System	05 Sep 2020 14:53:11
	System	05 Sep 2020 14:53:11

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	06 Sep 2020 04:12:03
	System	06 Sep 2020 04:12:03

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	06 Sep 2020 04:12:03
	System	06 Sep 2020 04:12:03

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	06 Sep 2020 04:12:03
	System	06 Sep 2020 04:12:03

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	06 Sep 2020 04:12:03
	System	06 Sep 2020 04:12:03

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	06 Sep 2020 04:12:03
	System	06 Sep 2020 04:12:03

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	06 Sep 2020 04:12:03
	System	06 Sep 2020 04:12:03

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	06 Sep 2020 04:12:03
	System	06 Sep 2020 04:12:03

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '05 Sep 2020 23:11'	System	06 Sep 2020 04:12:03
	System	06 Sep 2020 04:12:03

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	07 Sep 2020 01:48:37
	System	07 Sep 2020 01:48:37

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	07 Sep 2020 01:48:37
	System	07 Sep 2020 01:48:37

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	07 Sep 2020 01:48:37
	System	07 Sep 2020 01:48:37

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	07 Sep 2020 01:48:37
	System	07 Sep 2020 01:48:37

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	07 Sep 2020 01:48:37
	System	07 Sep 2020 01:48:37

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	System	07 Sep 2020 01:48:37
	System	07 Sep 2020 01:48:37

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	System	07 Sep 2020 01:48:37
	System	07 Sep 2020 01:48:37

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered '06 Sep 2020 20:48'	System	07 Sep 2020 01:48:37
	System	07 Sep 2020 01:48:37

US3812059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	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: 10 Jun 2021 09:51:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	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: 10 Jun 2021 09:51:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	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: 10 Jun 2021 09:51:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	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: 10 Jun 2021 09:51:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	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: 10 Jun 2021 09:51:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'None (0)'	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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	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: 10 Jun 2021 09:51:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Karen Knapp (b) (4)	09 Sep 2020 11:56:28

US3812059

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:21

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	10 Nov 2020 17:41:00
User entered '8 Sep 2020'	(b) (4)	
	Karen Knapp (b) (4)	09 Sep 2020 11:56:28
	(b) (4)	

US3812059

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	09 Sep 2020 11:56:28

US3812059

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered empty.	Karen Knapp (b) (4)	09 Sep 2020 11:56:28

US3812059

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Karen Knapp (b) (4)	13 Sep 2020 14:14:56

US3812059

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User entered '1'	System	13 Sep 2020 14:14:56

US3812059

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Karen Knapp (b) (4)	15 Sep 2020 20:39:30

US3812059

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '15 Sep 2020'	Karen Knapp (b) (4)	15 Sep 2020 20:39:30

US3812059

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	15 Sep 2020 20:39:30

US3812059

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered empty.	Karen Knapp (b) (4)	15 Sep 2020 20:39:30

US3812059

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Karen Knapp (b) (4)	15 Sep 2020 20:39:34

US3812059

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User entered '1'	System	15 Sep 2020 20:39:34

US3812059

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Karen Knapp (b) (4)	22 Sep 2020 21:55:26

US3812059

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '22 Sep 2020'	Karen Knapp (b) (4)	22 Sep 2020 21:55:26

US3812059

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	22 Sep 2020 21:55:26

US3812059

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered empty.	Karen Knapp (b) (4)	22 Sep 2020 21:55:26

US3812059

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Karen Knapp (b) (4)	22 Sep 2020 21:55:30

US3812059

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User entered '1'	System	22 Sep 2020 21:55:30

US3812059

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	02 Oct 2020 15:46:48

US3812059

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '30 Sep 2020'	Breanna Galibert (b) (4)	02 Oct 2020 15:46:48

US3812059

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4)	02 Oct 2020 15:46:48

US3812059

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User entered 'VISIT3'	System	02 Oct 2020 15:46:48

US3812059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	02 Oct 2020 15:47:17

US3812059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '30 Sep 2020'	Breanna Galibert (b) (4)	02 Oct 2020 15:47:17

US3812059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '15:56'	Breanna Galibert (b) (4)	02 Oct 2020 15:47:17

US3812059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
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: 10 Jun 2021 09:51:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '98.1' F	Breanna Galibert (b) (4)	02 Oct 2020 15:47:17

US3812059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Oral (Oral)'	Breanna Galibert (b) (4)	02 Oct 2020 15:47:17

US3812059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered empty.	Breanna Galibert (b) (4)	02 Oct 2020 15:47:17

US3812059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '92'	Breanna Galibert (b) (4)	02 Oct 2020 15:47:17

US3812059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User entered 'bpm'	System	02 Oct 2020 15:47:17

US3812059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '14'	Breanna Galibert (b) (4)	02 Oct 2020 15:47:17

US3812059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User entered 'breaths/min'	System	02 Oct 2020 15:47:17

US3812059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '102'	Breanna Galibert (b) (4)	02 Oct 2020 15:47:17

US3812059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User entered 'mmHg'	System	02 Oct 2020 15:47:17

US3812059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '60'	Breanna Galibert (b) (4)	02 Oct 2020 15:47:17

US3812059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User entered 'mmHg'	System	02 Oct 2020 15:47:17

US3812059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16

US3812059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16

US3812059

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:51:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'No (N)'	Breanna Galibert (b) (4)	02 Oct 2020 15:47:28

US3812059

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:51:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered empty.	Breanna Galibert (b) (4)	02 Oct 2020 15:47:28

US3812059

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	02 Oct 2020 15:47:51

US3812059

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
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) (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: 10 Jun 2021 09:51:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '16:10'	Breanna Galibert (b) (4)	02 Oct 2020 15:47:51

US3812059

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Karen Knapp (b) (4)	18 Oct 2020 15:28:41

US3812059

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User entered '1'	System	18 Oct 2020 15:28:41

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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
	System	08 Oct 2020 16:35:32

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	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: 10 Jun 2021 09:51:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	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: 10 Jun 2021 09:51:21

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
User closed query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM). Query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'Subject came in for illness visit. These symptoms are captured there' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 15:00:18
User opened query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	lauren clement (b) (4)	08 Mar 2021 20:40:42
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'	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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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' User entered 'No (N)'	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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: 10 Jun 2021 09:51:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:05
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: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17
Data entry locked.	System	06 Aug 2020 16:35:18
User entered 'Day 92'	System	06 Aug 2020 16:35:18

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

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Folder: Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 09:51:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

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Folder: Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

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Folder: Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
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Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
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Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

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Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17
Data entry locked.	System	06 Aug 2020 16:35:18
User entered '03 Nov 2020 00:01'	System	06 Aug 2020 16:35:18

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17
Data entry locked.	System	06 Aug 2020 16:35:18
User entered '07 Nov 2020 23:59'	System	06 Aug 2020 16:35:18

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Folder: Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17
Data entry locked.	System	06 Aug 2020 16:35:18
User entered 'Day 99'	System	06 Aug 2020 16:35:18

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[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)
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Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
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[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
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US3812059

Folder: Safety Follow Up Diary (1)

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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Folder: Safety Follow Up Diary (1)

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[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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Folder: Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

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Folder: Safety Follow Up Diary (1)

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[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

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Folder: Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

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[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

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[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

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Folder: Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

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Folder: Safety Follow Up Diary (1)

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
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Audit	User	Time (GMT)
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[Date and time of submission](#)

Audit	User	Time (GMT)
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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17
Data entry locked.	System	06 Aug 2020 16:35:18
User entered '10 Nov 2020 00:01'	System	06 Aug 2020 16:35:18

US3812059

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17
Data entry locked.	System	06 Aug 2020 16:35:18
User entered '14 Nov 2020 23:59'	System	06 Aug 2020 16:35:18

US3812059

Folder: Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17
Data entry locked.	System	06 Aug 2020 16:35:18
User entered 'Day 106'	System	06 Aug 2020 16:35:18

US3812059

Folder: Safety Follow Up Diary (1)

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[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)
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Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17
Data entry locked.	System	06 Aug 2020 16:35:18
User entered '17 Nov 2020 00:01'	System	06 Aug 2020 16:35:18

US3812059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:33:17
Data entry locked.	System	06 Aug 2020 16:35:18
User entered '21 Nov 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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16
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: 10 Jun 2021 09:51:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 09:51:21

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
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US3812059

Folder: New Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 09:51:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16
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: 10 Jun 2021 09:51:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16
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: 10 Jun 2021 09:51:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 09:51:21

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 09:51:21

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
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US3812059

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16
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: 10 Jun 2021 09:51:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
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US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16
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: 10 Jun 2021 09:51:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16
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: 10 Jun 2021 09:51:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2021-03-15T09:54:55-05:00', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '401d93e2-d247-4c5f-9d7d-fa17cdd1d852'	System	15 Mar 2021 14:55:30
User entered 'Yes (Y)'	System	15 Mar 2021 14:55:30
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2021-03-15T09:55:04-05:00', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '401d93e2-d247-4c5f-9d7d-fa17cdd1d852'	System	15 Mar 2021 14:55:30
User entered 'No (N)'	System	15 Mar 2021 14:55:30
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2021-03-15T09:55:10-05:00', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '401d93e2-d247-4c5f-9d7d-fa17cdd1d852'	System	15 Mar 2021 14:55:30
User entered 'No (N)'	System	15 Mar 2021 14:55:30
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2021-03-15T09:55:23-05:00', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '401d93e2-d247-4c5f-9d7d-fa17cdd1d852'	System	15 Mar 2021 14:55:30
User entered 'No (N)'	System	15 Mar 2021 14:55:30
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2021-03-15T09:55:27-05:00', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '401d93e2-d247-4c5f-9d7d-fa17cdd1d852'	System	15 Mar 2021 14:55:30
User entered '15 Mar 2021 09:55:27'	System	15 Mar 2021 14:55:30
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16
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

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16
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: 10 Jun 2021 09:51:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2021-03-21T13:39:01-05:00', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '38039c31-68b3-4fea-86f7-a48cd419703e'	System	21 Mar 2021 18:39:12
User entered 'No (N)'	System	21 Mar 2021 18:39:12
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2021-03-21T13:39:06-05:00', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '38039c31-68b3-4fea-86f7-a48cd419703e'	System	21 Mar 2021 18:39:12
User entered 'No (N)'	System	21 Mar 2021 18:39:12
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2021-03-21T13:39:09-05:00', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '38039c31-68b3-4fea-86f7-a48cd419703e'	System	21 Mar 2021 18:39:12
User entered '21 Mar 2021 13:39:09'	System	21 Mar 2021 18:39:12
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16

US3812059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16
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: 10 Jun 2021 09:51:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Activated.	System	15 Mar 2021 14:11:49
DataPoint Inactivated.	System	01 Feb 2021 12:43:16
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: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:51:21

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:37:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2021-03-15T09:55:33-05:00', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '9074784a-bae2-433a-aa82-500248fdf5a4'	System	15 Mar 2021 14:55:38
User entered 'No (N)'	System	15 Mar 2021 14:55:38

US3812059

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:51:21

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:37:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ED195E4-1B03-4273-9F51-54989A12D08A)', Time: '2021-03-15T09:55:36-05:00', User OID: 'PatientReportedOutcome (US3812059)', ODM File OID: '9074784a-bae2-433a-aa82-500248fdf5a4' User entered '15 Mar 2021 09:55:36'	System	15 Mar 2021 14:55:38
	System	15 Mar 2021 14:55:38

US3812059

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Karen Knapp (b) (4)	28 Oct 2020 19:27:55

US3812059

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '28 Oct 2020'	Karen Knapp (b) (4)	28 Oct 2020 19:27:55

US3812059

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	28 Oct 2020 19:27:55

US3812059

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered empty.	Karen Knapp (b) (4)	28 Oct 2020 19:27:55

US3812059

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Karen Knapp (b) (4)	28 Oct 2020 19:27:59

US3812059

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:45:16
User entered '1'	System	28 Oct 2020 19:27:59

US3812059

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered 'Yes (Y)'	Lyly Dang (b) (4)	29 Jan 2021 16:22:58

US3812059

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:21

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User closed query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	29 Jan 2021 17:51:06
Query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered by data change (Site from System).	System	29 Jan 2021 17:51:06
User entered '30 Nov 2020' reason for change: Data Entry Error	Lyly Dang (b) (4)	29 Jan 2021 17:51:06
User opened query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	29 Jan 2021 16:22:58
User entered '30 Dec 2020'	Lyly Dang (b) (4)	29 Jan 2021 16:22:58

US3812059

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered 'Contact Not Made (CONTACT NOT MADE)'	Lyly Dang (b) (4)	29 Jan 2021 16:22:58

US3812059

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered 'Subject did not pick up site's call or return site's call'	Lyly Dang (b) (4)	29 Jan 2021 16:22:58

US3812059

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered 'Yes (Y)'	Lyly Dang (b) (4)	29 Jan 2021 17:51:13

US3812059

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:38
User entered '1'	System	29 Jan 2021 17:51:13

US3812059

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:06:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered 'Yes (Y)'	Lyly Dang (b) (4)	29 Jan 2021 17:56:24

US3812059

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:21

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:06:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered '31 Dec 2020'	Lyly Dang (b) (4)	29 Jan 2021 17:56:24

US3812059

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:06:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered 'Contact Not Made (CONTACT NOT MADE)'	Lyly Dang (b) (4)	29 Jan 2021 17:56:24

US3812059

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:06:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered 'Subject did not pick up site's call or return site's call'	Lyly Dang (b) (4)	29 Jan 2021 17:56:24

US3812059

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:06:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered 'Yes (Y)'	Lyly Dang (b) (4)	29 Jan 2021 17:56:50

US3812059

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:06:47
User entered '1'	System	29 Jan 2021 17:56:50

US3812059

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:03:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Yes (Y)'	Lyly Dang (b) (4)	29 Jan 2021 17:59:14

US3812059

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:21

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:03:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered '29 Jan 2021'	Lyly Dang (b) (4)	29 Jan 2021 17:59:14

US3812059

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:03:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Contact Not Made (CONTACT NOT MADE)'	Lyly Dang (b) (4)	29 Jan 2021 17:59:14

US3812059

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:03:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:03
User entered 'Subject did not pick up site's call or return site's call'	Lyly Dang (b) (4)	29 Jan 2021 17:59:14

US3812059

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:03:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered 'No (N)'	Lyly Dang (b) (4)	01 Feb 2021 12:44:33

US3812059

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:03:24
User entered empty.	System	01 Feb 2021 12:44:33

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:51:21

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '08 Oct 2020' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	10 Nov 2020 17:42:14
	(b) (4)	
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
	(b) (4)	
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
	(b) (4)	
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
	(b) (4)	
User entered '8 Oct 2020'	Breanna Galibert (b) (4)	16 Oct 2020 22:45:44
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:51:21

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '16:59'	Breanna Galibert (b) (4)	16 Oct 2020 22:45:44
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:51:21

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Breanna Galibert (b) (4)	16 Oct 2020 22:45:44
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:51:21

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	16 Oct 2020 22:45:44
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Day 1 (Day 1)'	Breanna Galibert (b) (4)	16 Oct 2020 22:46:49
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '08 Oct 2020'	Breanna Galibert (b) (4)	16 Oct 2020 22:46:49
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	16 Oct 2020 22:46:49
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User closed query 'Per CDM: It appears that O2 Saturation and temperature are missing for Days 1-8. If not collected, please consider recording these as Not Done.	(b) (4), (b) (6)	20 Jan 2021 08:45:00
' (Site from DM).		
Query 'Per CDM: It appears that O2 Saturation and temperature are missing for Days 1-8. If not collected, please consider recording these as Not Done.	Breanna Galibert (b) (4)	18 Jan 2021 18:09:55
	(b) (4)	
' answered with 'updated' (Site from DM).		
User entered missing code ND - Not Done; reason for change Per Query Resolution	Breanna Galibert (b) (4)	18 Jan 2021 18:09:44
	(b) (4)	
User opened query 'Per CDM: It appears that O2 Saturation and temperature are missing for Days 1-8. If not collected, please consider recording these as Not Done.	(b) (4), (b) (6)	18 Jan 2021 13:29:59
' (Site from DM).		
User entered empty.	Breanna Galibert (b) (4)	16 Oct 2020 22:46:49
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '%'	System	18 Jan 2021 18:09:44
User entered empty.	System	16 Oct 2020 22:46:49

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Breanna Galibert (b) (4)	18 Jan 2021 18:09:44
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	16 Oct 2020 22:46:49
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	16 Oct 2020 22:46:49
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:46:49
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:46:49
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:46:49
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	16 Oct 2020 22:46:49
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	16 Oct 2020 22:46:49
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	16 Oct 2020 22:46:49
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	16 Oct 2020 22:46:49
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:46:49
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:46:49
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	16 Oct 2020 22:46:49
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	16 Oct 2020 22:46:49
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:46:49
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:46:49
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	16 Oct 2020 22:46:49
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	16 Oct 2020 22:46:49
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Day 2 (Day 2)'	Breanna Galibert (b) (4)	16 Oct 2020 22:47:25
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '09 Oct 2020'	Breanna Galibert (b) (4)	16 Oct 2020 22:47:25
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	16 Oct 2020 22:47:25
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Breanna Galibert (b) (4)	18 Jan 2021 18:09:44
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	16 Oct 2020 22:47:25
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '%'	System	18 Jan 2021 18:09:44
User entered empty.	System	16 Oct 2020 22:47:25

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Breanna Galibert (b) (4)	18 Jan 2021 18:09:44
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	16 Oct 2020 22:47:25
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	16 Oct 2020 22:47:25
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:47:25
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:47:25
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:47:25
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	16 Oct 2020 22:47:25
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	16 Oct 2020 22:47:25
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	16 Oct 2020 22:47:25
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	16 Oct 2020 22:47:25
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:47:25
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:47:25
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	16 Oct 2020 22:47:25
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	16 Oct 2020 22:47:25
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:47:25
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:47:25
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	16 Oct 2020 22:47:25
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	16 Oct 2020 22:47:25
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Day 3 (Day 3)'	Breanna Galibert (b) (4)	16 Oct 2020 22:48:03
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '10 Oct 2020'	Breanna Galibert (b) (4)	16 Oct 2020 22:48:03
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	16 Oct 2020 22:48:03
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Breanna Galibert (b) (4)	18 Jan 2021 18:09:44
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	16 Oct 2020 22:48:03
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '%'	System	18 Jan 2021 18:09:44
User entered empty.	System	16 Oct 2020 22:48:03

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Breanna Galibert (b) (4)	18 Jan 2021 18:09:44
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	16 Oct 2020 22:48:03
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	16 Oct 2020 22:48:03
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:48:03
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:48:03
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:48:03
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	16 Oct 2020 22:48:03
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	16 Oct 2020 22:48:03
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	16 Oct 2020 22:48:03
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	16 Oct 2020 22:48:03
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:48:03
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:48:03
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	16 Oct 2020 22:48:03
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	16 Oct 2020 22:48:03
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:48:03
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:48:03
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	16 Oct 2020 22:48:03
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	16 Oct 2020 22:48:03
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Day 4 (Day 4)'	Breanna Galibert (b) (4)	16 Oct 2020 22:48:36
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '11 Oct 2020'	Breanna Galibert (b) (4)	16 Oct 2020 22:48:36
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	16 Oct 2020 22:48:36
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Breanna Galibert (b) (4)	18 Jan 2021 18:09:44
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	16 Oct 2020 22:48:36
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '%'	System	18 Jan 2021 18:09:44
User entered empty.	System	16 Oct 2020 22:48:36

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Breanna Galibert (b) (4)	18 Jan 2021 18:09:44
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	16 Oct 2020 22:48:36
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	16 Oct 2020 22:48:36
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:48:36
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:48:36
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:48:36
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	16 Oct 2020 22:48:36
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	16 Oct 2020 22:48:36
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	16 Oct 2020 22:48:36
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	16 Oct 2020 22:48:36
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:48:36
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:48:36
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	16 Oct 2020 22:48:36
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	16 Oct 2020 22:48:36
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:48:36
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:48:36
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:48:36
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	16 Oct 2020 22:48:36
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Day 5 (Day 5)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:21
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '12 Oct 2020'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:21
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:21
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Breanna Galibert (b) (4)	18 Jan 2021 18:09:44
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	16 Oct 2020 22:49:21
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '%'	System	18 Jan 2021 18:09:44
User entered empty.	System	16 Oct 2020 22:49:21

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Breanna Galibert (b) (4)	18 Jan 2021 18:09:44
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	16 Oct 2020 22:49:21
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:21
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:21
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:21
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:21
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:21
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:21
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:21
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:21
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:21
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:21
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:21
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:21
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:21
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:21
	(b) (4)	

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Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:21
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:21
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Day 6 (Day 6)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:36
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '13 Oct 2020'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:36
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:36
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Breanna Galibert (b) (4)	18 Jan 2021 18:09:44
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	16 Oct 2020 22:49:36
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '%'	System	18 Jan 2021 18:09:44
User entered empty.	System	16 Oct 2020 22:49:36

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Breanna Galibert (b) (4)	18 Jan 2021 18:09:44
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	16 Oct 2020 22:49:36
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:36
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:36
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:36
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:36
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:36
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:36
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:36
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:36
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:36
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:36
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:36
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:36
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:36
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:36
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:36
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:36
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Day 7 (Day 7)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:54
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '14 Oct 2020'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:54
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:54
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Breanna Galibert (b) (4)	18 Jan 2021 18:09:44
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	16 Oct 2020 22:49:54
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '%'	System	18 Jan 2021 18:09:44
User entered empty.	System	16 Oct 2020 22:49:54

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Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Breanna Galibert (b) (4)	18 Jan 2021 18:09:44
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	16 Oct 2020 22:49:54
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:54
	(b) (4)	

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Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:54
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:54
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:54
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:54
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:54
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:54
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:54
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:54
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:54
	(b) (4)	

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Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:54
	(b) (4)	

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Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:54
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:54
	(b) (4)	

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Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:54
	(b) (4)	

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Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:54
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:49:54
	(b) (4)	

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Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Day 8 (Day 8)'	Breanna Galibert (b) (4)	16 Oct 2020 22:50:09
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '15 Oct 2020'	Breanna Galibert (b) (4)	16 Oct 2020 22:50:09
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	16 Oct 2020 22:50:09
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Breanna Galibert (b) (4)	18 Jan 2021 18:09:44
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	16 Oct 2020 22:50:09
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '%'	System	18 Jan 2021 18:09:44
User entered empty.	System	16 Oct 2020 22:50:09

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Breanna Galibert (b) (4)	18 Jan 2021 18:09:44
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	16 Oct 2020 22:50:09
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:50:09
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:50:09
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:50:09
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:50:09
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:50:09
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:50:09
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:50:09
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:50:09
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:50:09
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:50:09
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:50:09
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:50:09
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:50:09
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:50:09
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:50:09
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:50:09
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Day 9 (Day 9)'	Breanna Galibert (b) (4)	16 Oct 2020 22:50:33
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '16 Oct 2020'	Breanna Galibert (b) (4)	16 Oct 2020 22:50:33
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	16 Oct 2020 22:50:33
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '98'	Breanna Galibert (b) (4)	16 Oct 2020 22:50:33
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '%'	System	16 Oct 2020 22:50:33

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '99.1' F	Breanna Galibert (b) (4)	16 Oct 2020 22:50:33
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:50:33
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:50:33
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:50:33
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:50:33
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:50:33
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:50:33
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:50:33
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:50:33
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:50:33
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:50:33
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:50:33
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:50:33
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:50:33
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:50:33
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:50:33
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Oct 2020 22:50:33
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Day 10 (Day 10)'	Breanna Galibert (b) (4)	20 Oct 2020 15:15:15
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '17 Oct 2020'	Breanna Galibert (b) (4)	20 Oct 2020 15:15:15
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	20 Oct 2020 15:15:15
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '97'	Breanna Galibert (b) (4)	20 Oct 2020 15:15:15
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '%'	System	20 Oct 2020 15:15:15

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '98.6' F	Breanna Galibert (b) (4)	20 Oct 2020 15:15:15
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:15:15
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:15:15
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:15:15
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:15:15
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:15:15
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:15:15
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:15:15
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:15:15
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:15:15
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:15:15
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:15:15
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:15:15
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:15:15
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:15:15
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:15:15
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:15:15
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Day 11 (Day 11)'	Breanna Galibert (b) (4)	20 Oct 2020 15:15:41
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '18 Oct 2020'	Breanna Galibert (b) (4)	20 Oct 2020 15:15:41
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	20 Oct 2020 15:15:41
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '96'	Breanna Galibert (b) (4)	20 Oct 2020 15:15:41
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '%'	System	20 Oct 2020 15:15:41

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '98.6' F	Breanna Galibert (b) (4)	20 Oct 2020 15:15:41
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:15:41
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:15:41
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:15:41
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:15:41
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:15:41
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:15:41
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:15:41
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:15:41
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:15:41
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:15:41
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:15:41
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:15:41
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:15:41
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:15:41
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:15:41
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:15:41
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Day 12 (Day 12)'	Breanna Galibert (b) (4)	20 Oct 2020 15:16:15
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '19 Oct 2020'	Breanna Galibert (b) (4)	20 Oct 2020 15:16:15
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	20 Oct 2020 15:16:15
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '97'	Breanna Galibert (b) (4)	20 Oct 2020 15:16:15
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '%'	System	20 Oct 2020 15:16:15

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '98.7' F	Breanna Galibert (b) (4)	20 Oct 2020 15:16:15
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:16:15
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:16:15
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:16:15
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:16:15
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:16:15
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:16:15
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:16:15
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:16:15
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:16:15
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:16:15
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:16:15
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:16:15
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:16:15
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:16:15
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:16:15
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	20 Oct 2020 15:16:15
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:51:21

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '16 Oct 2020' reason for change: Data Entry Error	Angie Kean (b) (4)	17 Feb 2021 16:05:53
	(b) (4)	
User entered '11 Oct 2020' reason for change: Data Entry Error	Breanna Galibert (b) (4)	10 Feb 2021 20:07:46
	(b) (4)	
User entered '16 Oct 2020'	Breanna Galibert (b) (4)	16 Oct 2020 22:51:02
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:51:21

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	16 Oct 2020 22:51:02
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:51:21

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	16 Oct 2020 22:51:02
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:51:21

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User closed query 'Per GCL Lab Recon: Nasopharyngeal Swab: Sample dated 11OCT2020 is recorded under Covid-19 Assessment Visit in EDC, however the sample is missing in PPD Central lab. Please confirm if the sample has been shipped and provide Accession number and Tracking details in the response. Thank you.	(b) (4), (b) (6)	26 Feb 2021 07:05:56
' (Site from DM). User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
Query 'Per GCL Lab Recon: Nasopharyngeal Swab: Sample dated 11OCT2020 is recorded under Covid-19 Assessment Visit in EDC, however the sample is missing in PPD Central lab. Please confirm if the sample has been shipped and provide Accession number and Tracking details in the response. Thank you.	Angie Kean (b) (4)	17 Feb 2021 16:06:02
' answered with 'updated to correct collection date' (Site from DM). User entered '16 Oct 2020' reason for change: Data Entry Error	Angie Kean (b) (4)	17 Feb 2021 16:05:53
User opened query 'Per GCL Lab Recon: Nasopharyngeal Swab: Sample dated 11OCT2020 is recorded under Covid-19 Assessment Visit in EDC, however the sample is missing in PPD Central lab. Please confirm if the sample has been shipped and provide Accession number and Tracking details in the response. Thank you.	(b) (4), (b) (6)	29 Jan 2021 07:34:44
' (Site from DM). User entered '11 Oct 2020'	Breanna Galibert (b) (4)	16 Oct 2020 22:51:02

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:51:21

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Breanna Galibert (b) (4)	16 Oct 2020 22:51:02
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:51:21

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	16 Oct 2020 22:51:02
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:51:21

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Breanna Galibert (b) (4)	10 Feb 2021 20:07:46
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	16 Oct 2020 22:51:02
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:51:21

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	10 Feb 2021 20:07:46
	(b) (4)	
User entered 'BJC'	Breanna Galibert (b) (4)	16 Oct 2020 22:51:02
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:51:21

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	10 Feb 2021 20:07:46
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	16 Oct 2020 22:51:02
	(b) (4)	

US3812059

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:51:21

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'No (N)'	Heather Cherniawski	26 Oct 2020 19:45:23
	(b) (4)	

US3812059

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:51:21

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:01:33
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: 10 Jun 2021 09:51:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:01:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered 'Yes (Y)'	Angie Kean (b) (4)	30 Oct 2020 22:38:26

US3812059

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:51:21

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:01:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered '18 Oct 2020'	Angie Kean (b) (4)	30 Oct 2020 22:38:26

US3812059

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:51:21

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:01:33
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: 10 Jun 2021 09:51:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:01:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered 'NA (COVID-19 Negative) (NA)'	Angie Kean (b) (4)	30 Oct 2020 22:38:26

US3812059

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:51:21

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:01:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered empty.	Angie Kean (b) (4)	30 Oct 2020 22:38:26

US3812059

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:51:21

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:01:33
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: 10 Jun 2021 09:51:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:01:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered 'NA (COVID-19 Negative) (NA)'	Angie Kean (b) (4)	30 Oct 2020 22:38:26

US3812059

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:51:21

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:01:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered empty.	Angie Kean (b) (4)	30 Oct 2020 22:38:26

US3812059

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:51:21

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:01:33
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: 10 Jun 2021 09:51:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:01:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered 'NA (COVID-19 Negative) (NA)'	Angie Kean (b) (4)	30 Oct 2020 22:38:26

US3812059

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:51:21

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:01:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered empty.	Angie Kean (b) (4)	30 Oct 2020 22:38:26

US3812059

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:51:21

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:01:33
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: 10 Jun 2021 09:51:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:01:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered 'NA (COVID-19 Negative) (NA)'	Angie Kean (b) (4)	30 Oct 2020 22:38:26

US3812059

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:51:21

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:01:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered empty.	Angie Kean (b) (4)	30 Oct 2020 22:38:26

US3812059

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:51:21

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:01:33
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: 10 Jun 2021 09:51:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:01:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered 'NA (COVID-19 Negative) (NA)'	Angie Kean (b) (4)	30 Oct 2020 22:38:26

US3812059

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:51:21

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:01:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered empty.	Angie Kean (b) (4)	30 Oct 2020 22:38:26

US3812059

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:51:21

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:01:33
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: 10 Jun 2021 09:51:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:01:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered 'NA (COVID-19 Negative) (NA)'	Angie Kean (b) (4)	30 Oct 2020 22:38:26

US3812059

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:51:21

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:01:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered empty.	Angie Kean (b) (4)	30 Oct 2020 22:38:26

US3812059

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:32
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered 'Yes (Y)'	Angie Kean (b) (4)	30 Oct 2020 22:24:43

US3812059

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:32
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered '16 Oct 2020'	Angie Kean (b) (4)	30 Oct 2020 22:24:43

US3812059

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:32
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered 'Clinic (Clinic)'	Angie Kean (b) (4)	30 Oct 2020 22:24:43

US3812059

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:32
User entered 'SICKD1'	System	30 Oct 2020 22:24:43

US3812059

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered 'Yes (Y)'	Angie Kean (b) (4)	30 Oct 2020 22:25:18

US3812059

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered '16 Oct 2020'	Angie Kean (b) (4)	30 Oct 2020 22:25:18

US3812059

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered '17:01'	Angie Kean (b) (4)	30 Oct 2020 22:25:18

US3812059

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:42
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: 10 Jun 2021 09:51:21

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered '64.8' in	Angie Kean (b) (4)	30 Oct 2020 22:25:18
DataPoint set to visible.	System	30 Oct 2020 22:24:43

US3812059

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:21

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered '136.7' lb	Angie Kean (b) (4)	30 Oct 2020 22:25:18
DataPoint set to visible.	System	30 Oct 2020 22:24:43

US3812059

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered '99.1' F	Angie Kean (b) (4)	30 Oct 2020 22:25:18

US3812059

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered 'Oral (Oral)'	Angie Kean (b) (4)	30 Oct 2020 22:25:18

US3812059

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered empty.	Angie Kean (b) (4)	30 Oct 2020 22:25:18

US3812059

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered '86'	Angie Kean (b) (4)	30 Oct 2020 22:25:18

US3812059

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:42
User entered 'bpm'	System	30 Oct 2020 22:25:18

US3812059

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered '14'	Angie Kean (b) (4)	30 Oct 2020 22:25:18

US3812059

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:42
User entered 'breaths/min'	System	30 Oct 2020 22:25:18

US3812059

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered '96'	Angie Kean (b) (4)	30 Oct 2020 22:25:18

US3812059

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:42
User entered 'mmHg'	System	30 Oct 2020 22:25:18

US3812059

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered '70'	Angie Kean (b) (4)	30 Oct 2020 22:25:18

US3812059

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:42
User entered 'mmHg'	System	30 Oct 2020 22:25:18

US3812059

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:42

US3812059

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:42

US3812059

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:51:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:51
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered 'Yes (Y)'	Angie Kean (b) (4)	30 Oct 2020 22:25:30

US3812059

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:51:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:51
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered '16 Oct 2020'	Angie Kean (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: 10 Jun 2021 09:51:21

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:01:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered 'Yes (Y)'	Angie Kean (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: 10 Jun 2021 09:51:21

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:01:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered '16 Oct 2020'	Angie Kean (b) (4)	30 Oct 2020 22:25:38

US3812059

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

Form: Visit Date

Generated On: 10 Jun 2021 09:51:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'No (N)'	Lyly Dang (b) (4)	29 Jan 2021 18:02:14

US3812059

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

Form: Visit Date

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered empty.	Lyly Dang (b) (4)	29 Jan 2021 18:02:14

US3812059

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

Form: Visit Date

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered empty.	Lyly Dang (b) (4)	29 Jan 2021 18:02:14

US3812059

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

Form: Visit Date

Generated On: 10 Jun 2021 09:51:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered 'UNBLND_DECIDE'	System	29 Jan 2021 18:02:14

US3812059

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

Form: Unblinding

Generated On: 10 Jun 2021 09:51:21

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User closed query 'Per CDM: Informed Consent Date is missing. Kindly review and update else clarify. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 11:21:24
Query 'Per CDM: Informed Consent Date is missing. Kindly review and update else clarify. ' answered with 'subject did not sign new consent; did not receive mRNA-1273' (Site from DM).	Breanna Galibert (b) (4)	23 Apr 2021 14:05:22
User opened query 'Per CDM: Informed Consent Date is missing. Kindly review and update else clarify. ' (Site from DM).	(b) (4)	22 Apr 2021 13:22:53
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	06 Mar 2021 16:21:13
Amendment Manager: User opened query 'Data is required. Please complete.' (Site from System).	System	27 Feb 2021 15:34:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	01 Feb 2021 04:46:16
Query 'Data is required. Please complete.' answered with 'N/A' (Site from System).	Lyly Dang (b) (4)	29 Jan 2021 18:02:34
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Jan 2021 18:02:26
User entered empty.	Lyly Dang (b) (4)	29 Jan 2021 18:02:26

US3812059

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

Form: Unblinding

Generated On: 10 Jun 2021 09:51:21

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 16:26:03
User entered '0'	Angie Kean (b) (4)	08 Apr 2021 14:50:08
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:21:14

US3812059

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

Form: Unblinding

Generated On: 10 Jun 2021 09:51:21

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User closed query 'Per IRT, Subject was unblinded. Please complete unblinding eCRF else clarify.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 00:39:53
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 16:26:03
Query 'Per IRT, Subject was unblinded. Please complete unblinding eCRF else clarify.' answered with 'updated' (Site from DM).	Angie Kean (b) (4)	08 Apr 2021 14:50:25
Signature has been broken.	(b) (4)	
	Angie Kean (b) (4)	08 Apr 2021 14:50:08
User entered 'Yes (Y)' reason for change: New Information	(b) (4)	
	Angie Kean (b) (4)	08 Apr 2021 14:50:08
User opened query 'Per IRT, Subject was unblinded. Please complete unblinding eCRF else clarify.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 07:20:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'No (N)'	Lyly Dang (b) (4)	29 Jan 2021 18:02:26

US3812059

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

Form: Unblinding

Generated On: 10 Jun 2021 09:51:21

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 16:26:03
User entered 'Amendment 6 or later (Amendment 6 or later)'	Angie Kean (b) (4)	08 Apr 2021 14:50:08
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:21:14

US3812059

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

Form: Unblinding

Generated On: 10 Jun 2021 09:51:21

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 16:26:03
Signature has been broken.	Angie Kean (b) (4)	08 Apr 2021 14:50:08
	(b) (4)	
User entered '23 Mar 2021' reason for change: New Information	Angie Kean (b) (4)	08 Apr 2021 14:50:08
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered empty.	Lyly Dang (b) (4)	29 Jan 2021 18:02:26

US3812059

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

Form: Unblinding

Generated On: 10 Jun 2021 09:51:21

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User closed query 'Per CDM: Per IRT: This subjects who assigned placebo in IRT for Day 1 but in EDC says they received mRNA, that the dose was not administered, or the field is blank; Please review and reconcile and update the data as required. Thank you!' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 20:51:54
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 16:26:03
Query 'Per CDM: Per IRT: This subjects who assigned placebo in IRT for Day 1 but in EDC says they received mRNA, that the dose was not administered, or the field is blank; Please review and reconcile and update the data as required. Thank you!' answered with 'updated' (Site from DM).	Angie Kean (b) (4)	08 Apr 2021 14:50:52
Signature has been broken.	Angie Kean (b) (4)	08 Apr 2021 14:50:08
User entered 'Placebo (Placebo)' reason for change: New Information	Angie Kean (b) (4)	08 Apr 2021 14:50:08
User opened query 'Per CDM: Per IRT: This subjects who assigned placebo in IRT for Day 1 but in EDC says they received mRNA, that the dose was not administered, or the field is blank; Please review and reconcile and update the data as required. Thank you!' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 08:28:51
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered empty.	Lyly Dang (b) (4)	29 Jan 2021 18:02:26

US3812059

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

Form: Unblinding

Generated On: 10 Jun 2021 09:51:21

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User closed query 'Per CDM: Per IRT this subject received placebo for Day 1 Dosing. Please update data else clarifiy. Thank you!' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Lyly Dang (b) (4)	15 Apr 2021 20:52:07 08 Apr 2021 16:26:03
Query 'Per CDM: Per IRT this subject received placebo for Day 1 Dosing. Please update data else clarifiy. Thank you!' answered with 'updated' (Site from DM). Signature has been broken.	Angie Kean (b) (4) (b) (4) Angie Kean (b) (4) (b) (4)	08 Apr 2021 14:51:09 08 Apr 2021 14:50:08 08 Apr 2021 14:50:08
User entered 'Placebo (Placebo)' reason for change: New Information User opened query 'Per CDM: Per IRT this subject received placebo for Day 1 Dosing. Please update data else clarifiy. Thank you!' (Site from DM). Query 'Per CDM: Per IRT: This subject received placebo for Day 29 Dosing. Pelase update data else clarify.'" canceled (Site from DM). User opened query 'Per CDM: Per IRT: This subject received placebo for Day 29 Dosing. Pelase update data else clarify.'" (Site from DM). User signature succeeded.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6) Larkin Wadsworth (b) (4) (b) (4)	08 Apr 2021 09:18:37 08 Apr 2021 09:16:44 08 Apr 2021 08:37:07 20 Feb 2021 19:34:52
User entered empty.	Lyly Dang (b) (4)	29 Jan 2021 18:02:26

US3812059

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

Form: Unblinding

Generated On: 10 Jun 2021 09:51:21

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User closed query 'Per CDM: Per IRT: This subject received placebo for Day 29 Dosing. Pelase update data else clarify.' ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 20:52:08
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 16:26:03
Query 'Per CDM: Per IRT: This subject received placebo for Day 29 Dosing. Pelase update data else clarify.' ' answered with 'updated' (Site from DM).	Angie Kean (b) (4)	08 Apr 2021 14:51:26
Signature has been broken.	(b) (4)	
	Angie Kean (b) (4)	08 Apr 2021 14:50:08
User entered 'Placebo (Placebo)' reason for change: New Information	(b) (4)	
	Angie Kean (b) (4)	08 Apr 2021 14:50:08
User opened query 'Per CDM: Per IRT: This subject received placebo for Day 29 Dosing. Pelase update data else clarify.' ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 09:16:41
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered empty.	Lyly Dang (b) (4)	29 Jan 2021 18:02:26

US3812059

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

Form: Unblinding

Generated On: 10 Jun 2021 09:51:21

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 16:26:03
User closed query "Will participant receive mRNA-1273?' is missing. Please reconcile.' (Site from System).	System	08 Apr 2021 14:51:44
Query "Will participant receive mRNA-1273?' is missing. Please reconcile.' answered by data change (Site from System).	System	08 Apr 2021 14:51:44
Signature has been broken.	Angie Kean (b) (4)	08 Apr 2021 14:51:44
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Angie Kean (b) (4)	08 Apr 2021 14:51:44
	(b) (4)	
User opened query "Will participant receive mRNA-1273?' is missing. Please reconcile.' (Site from System).	System	08 Apr 2021 14:50:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered empty.	Lyly Dang (b) (4)	29 Jan 2021 18:02:26

US3812059

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

Form: Unblinding

Generated On: 10 Jun 2021 09:51:21

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '1'	System	08 Apr 2021 14:50:08
User entered empty.	System	29 Jan 2021 18:02:26

US3812059

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

Form: Unblinding

Generated On: 10 Jun 2021 09:51:21

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered empty.	System	29 Jan 2021 18:02:26

US3812059

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'No (N)'	Lyly Dang (b) (4)	29 Jan 2021 18:02:38

US3812059

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered empty.	Lyly Dang (b) (4)	29 Jan 2021 18:02:38

US3812059

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered empty.	Lyly Dang (b) (4)	29 Jan 2021 18:02:38

US3812059

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered empty.	System	29 Jan 2021 18:02:38

US3812059

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:51:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'No (N)'	Lyly Dang (b) (4)	29 Jan 2021 18:02:46

US3812059

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered empty.	Lyly Dang (b) (4)	29 Jan 2021 18:02:46

US3812059

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered empty.	Lyly Dang (b) (4)	29 Jan 2021 18:02:46

US3812059

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered empty.	System	29 Jan 2021 18:02:46

US3812059

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:51:21

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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
	(b) (4)	
User entered 'No (N)'	Karen Knapp (b) (4)	03 Sep 2020 12:36:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:21

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

US3812059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:21

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
	(b) (4)	
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
	(b) (4)	
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4)	23 Oct 2020 21:10:48
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Oct 2020 21:10:48
	(b) (4)	
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4)	02 Oct 2020 15:46:48
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Oct 2020 15:46:48
	(b) (4)	
Data point term sent to Coder	System	02 Oct 2020 15:46:09
User entered 'nausea'	Breanna Galibert (b) (4)	02 Oct 2020 15:45:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered empty.	System	02 Oct 2020 15:45:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:21

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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: 10 Jun 2021 09:51:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered empty.	System	02 Oct 2020 15:45:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:21

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'Grade 1/Mild (Grade 1/Mild)'	Breanna Galibert (b) (4)	02 Oct 2020 15:45:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:21

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:21

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:21

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:21

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:21

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4)	02 Oct 2020 15:45:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4)	02 Oct 2020 15:45:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:21

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:21

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:21

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:21

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '0'	System	02 Oct 2020 15:45:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '0'	System	02 Oct 2020 15:45:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:21

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:21

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:21

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User coded data point as SOC: Gastrointestinal disorders, HLGIT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\23.0.	Coder Import (b) (4)	02 Oct 2020 15:48:45
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Oct 2020 15:48:45
	(b) (4)	
Data point term sent to Coder	System	02 Oct 2020 15:47:12
User entered 'vomiting'	Breanna Galibert (b) (4)	02 Oct 2020 15:46:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered empty.	System	02 Oct 2020 15:46:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:21

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered empty.	System	02 Oct 2020 15:46:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:21

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'Grade 1/Mild (Grade 1/Mild)'	Breanna Galibert (b) (4)	02 Oct 2020 15:46:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:21

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:21

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:21

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:21

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:21

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4)	02 Oct 2020 15:46:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4)	02 Oct 2020 15:46:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:21

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:21

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '0'	System	02 Oct 2020 15:46:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '0'	System	02 Oct 2020 15:46:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:51:21

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

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Folder: Adverse Events

Form: Adverse Events (3)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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	System	29 Oct 2020 19:42:49
'USA-US111-2020-mRNA-1273-P301000006'		
User entered 'New'	(b) (4), (b) (6)	29 Oct 2020 19:42:49

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:21

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
User closed query 'Per DM CLR: Please review if this AE is a worsening of the recorded MH condition of Anxiety. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 17:19:46
Query 'Per DM CLR: Please review if this AE is a worsening of the recorded MH condition of Anxiety. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' answered with 'Although this was a worsening of her anxiety, the overall outcome was a formal diagnosis of Anxiety Disorder per MR review. Keep term as is. Thanks' (Site from DM).	lauren clement (b) (4)	08 Mar 2021 19:33:17
User opened query 'Per DM CLR: Please review if this AE is a worsening of the recorded MH condition of Anxiety. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 03:00:19
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.	Coder Import (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

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Folder: Adverse Events

Form: Adverse Events (3)

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[Adverse event](#)

Audit	User	Time (GMT)
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.	Coder Import (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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered empty.	System	28 Oct 2020 23:06:52

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '27 Oct 2020'	Lyly Dang (b) (4)	28 Oct 2020 23:06:52

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:21

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered empty.	System	28 Oct 2020 23:06:52

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Folder: Adverse Events

Form: Adverse Events (3)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:21

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:21

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:21

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (3)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (3)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (3)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (3)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (3)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:21

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:21

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:21

[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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

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[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). DataPoint Verified.		
	(b) (4), (b) (6)	06 Nov 2020 14:12:03
	(b) (4), (b) (6)	02 Nov 2020 16:08:31

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:21

[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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:21

[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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:21

[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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:21

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '1'	System	28 Oct 2020 23:06:52

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '1'	System	28 Oct 2020 23:06:52

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:21

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '0'	System	28 Oct 2020 23:06:52

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Folder: Adverse Events

Form: Adverse Events (4)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:21

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	01 Nov 2020 11:29:49
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	01 Nov 2020 11:29:49
	(b) (4)	
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)	30 Oct 2020 22:42:05
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	30 Oct 2020 22:42:05
	(b) (4)	
Data point term sent to Coder	System	30 Oct 2020 22:41:29
User entered 'NICOTINE ADDICTION'	Angie Kean (b) (4)	30 Oct 2020 22:41:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'Yes (Y)'	Angie Kean (b) (4)	30 Oct 2020 22:41:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'No (N)'	Angie Kean (b) (4)	30 Oct 2020 22:41:01
	(b) (4)	

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Form: Adverse Events (4)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'No (N)'	Angie Kean (b) (4)	30 Oct 2020 22:41:01
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '27 Oct 2020'	Angie Kean (b) (4)	30 Oct 2020 22:41:01
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered empty.	Angie Kean (b) (4)	30 Oct 2020 22:41:01
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered empty.	System	30 Oct 2020 22:41:01

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'Yes (Y)'	Angie Kean (b) (4)	30 Oct 2020 22:41:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered empty.	Angie Kean (b) (4)	30 Oct 2020 22:41:01
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:21

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered empty.	Angie Kean (b) (4)	30 Oct 2020 22:41:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered empty.	System	30 Oct 2020 22:41:01

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:21

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Angie Kean (b) (4)	30 Oct 2020 22:41:01
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'No (N)'	Angie Kean (b) (4)	30 Oct 2020 22:41:01
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:21

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '0'	Angie Kean (b) (4)	30 Oct 2020 22:41:01
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:21

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '0'	Angie Kean (b) (4)	30 Oct 2020 22:41:01
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '0'	Angie Kean (b) (4)	30 Oct 2020 22:41:01
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:21

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered empty.	Angie Kean (b) (4)	30 Oct 2020 22:41:01
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:21

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered empty.	Angie Kean (b) (4)	30 Oct 2020 22:41:01
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered empty.	Angie Kean (b) (4)	30 Oct 2020 22:41:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered empty.	Angie Kean (b) (4)	30 Oct 2020 22:41:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '0'	Angie Kean (b) (4)	30 Oct 2020 22:41:01
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '0'	Angie Kean (b) (4)	30 Oct 2020 22:41:01
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:21

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '0'	Angie Kean (b) (4)	30 Oct 2020 22:41:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'Not Related (NOT RELATED)'	Angie Kean (b) (4)	30 Oct 2020 22:41:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'Not Related (NOT RELATED)'	Angie Kean (b) (4)	30 Oct 2020 22:41:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered 'Not Applicable (NOT APPLICABLE)'	Angie Kean (b) (4)	30 Oct 2020 22:41:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:21

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '0'	Angie Kean (b) (4)	30 Oct 2020 22:41:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '1'	Angie Kean (b) (4)	30 Oct 2020 22:41:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered '0'	Angie Kean (b) (4)	30 Oct 2020 22:41:01
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:21

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	30 Oct 2020 22:41:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered empty.	Angie Kean (b) (4)	30 Oct 2020 22:41:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:21

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:58:31
User entered empty.	Angie Kean (b) (4)	30 Oct 2020 22:41:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:21

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '0'	System	30 Oct 2020 22:41:01

US3812059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '1'	System	30 Oct 2020 22:41:01

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:21

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:21

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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 'USA-US111-2020-mRNA-1273-P301000006'	(b) (4), (b) (6)	16 Nov 2020 16:16:15

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:21

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
User closed query 'Per DM CLR: Please review if this AE is a worsening of the recorded MH condition of Depression. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 14:08:47
Query 'Per DM CLR: Please review if this AE is a worsening of the recorded MH condition of Depression. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' answered with 'ok, keep AE term as is' (Site from DM).	lauren clement (b) (4)	08 Mar 2021 19:34:59
User opened query 'Per DM CLR: Please review if this AE is a worsening of the recorded MH condition of Depression. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 03:00:51
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31
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)	14 Nov 2020 05:13:44
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	14 Nov 2020 05:13:44
	(b) (4)	
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

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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: 10 Jun 2021 09:51:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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: 10 Jun 2021 09:51:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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: 10 Jun 2021 09:51:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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: 10 Jun 2021 09:51:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered empty.	System	14 Nov 2020 01:15:36

US3812059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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: 10 Jun 2021 09:51:21

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered empty.	System	14 Nov 2020 01:15:36

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:21

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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: 10 Jun 2021 09:51:21

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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
	(b) (4)	

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:21

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
Query 'PV Query: Please clarify on hospital admission date. On paper SAE form, the hospitalization admission date is reported as 19 Nov2020, and eCRF is reported as 18 Nov 2020.' canceled (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 16:06:43
User opened query 'PV Query: Please clarify on hospital admission date. On paper SAE form, the hospitalization admission date is reported as 19 Nov2020, and eCRF is reported as 18 Nov 2020.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 21:36:06
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

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:21

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (5)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:21

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (5)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Form: Adverse Events (5)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Generated On: 10 Jun 2021 09:51:21

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:21

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:21

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 16:06:54
Query 'PV Query: Did the subject have a medical history of major depressive disorder? Was the SAE considered a worsening of the subject's medical history of depressive disorder?' canceled (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 16:06:51
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 21:36:17
User opened query 'PV Query: Did the subject have a medical history of major depressive disorder? Was the SAE considered a worsening of the subject's medical history of depressive disorder?' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 21:35:52
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:31

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Folder: Adverse Events

Form: Adverse Events (5)

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[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

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[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

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '1'	System	14 Nov 2020 01:15:36

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '1'	System	14 Nov 2020 01:15:36

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:21

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '0'	System	14 Nov 2020 01:15:36

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:21

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

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Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:21

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	21 Nov 2020 01:17:34
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Nov 2020 01:17:34
	(b) (4)	
Data point term sent to Coder	System	21 Nov 2020 01:15:44
DataPoint Un-verified.	Anya Penly (b) (4)	21 Nov 2020 00:40:48
	(b) (4)	
Coding entries removed.	Anya Penly (b) (4)	21 Nov 2020 00:40:48
	(b) (4)	
User entered 'DISSOCIATIVE DISORDER' reason for change: Data Entry Error	Anya Penly (b) (4)	21 Nov 2020 00:40:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	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)	14 Nov 2020 05:51:44
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	14 Nov 2020 05:51:44
	(b) (4)	
Data point term sent to Coder	System	14 Nov 2020 01:26:10
User entered 'Dissociation Disorder'	Lyly Dang (b) (4)	14 Nov 2020 01:25:29

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

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Generated On: 10 Jun 2021 09:51:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (6)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered empty.	System	14 Nov 2020 01:25:29

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Folder: Adverse Events

Form: Adverse Events (6)

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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
	(b) (4)	

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:21

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (6)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered empty.	System	14 Nov 2020 01:25:29

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:21

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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).		14 Nov 2020 01:25:29
User entered 'No (N)'	Lyly Dang (b) (4)	14 Nov 2020 01:25:29

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Folder: Adverse Events

Form: Adverse Events (6)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (6)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:21

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:21

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:21

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:21

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
DataPoint Un-verified.	lauren clement (b) (4)	08 Mar 2021 19:39:28
User entered '1' reason for change: Per Query Resolution	lauren clement (b) (4)	08 Mar 2021 19:39:28
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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please update to record the corresponding ConMed treatment for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 14:45:56
DataPoint Un-verified.	lauren clement (b) (4)	08 Mar 2021 19:39:28
User entered '0' reason for change: Per Query Resolution	lauren clement (b) (4)	08 Mar 2021 19:39:28
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please update to record the corresponding ConMed treatment for this AE as appropriate. Otherwise, clarify.' answered with 'ok' (Site from DM).	lauren clement (b) (4)	08 Mar 2021 19:39:06
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please update to record the corresponding ConMed treatment for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 03:00:35
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

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Folder: Adverse Events

Form: Adverse Events (6)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:21

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:21

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:21

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '0'	System	14 Nov 2020 01:25:29

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '1'	System	14 Nov 2020 01:25:29

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:21

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:51:21

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:36:16
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 15:15:48
User entered	System	21 Nov 2020 15:15:12
'USA-US111-2020-mRNA-1273-P301000013'		
User entered 'New'	(b) (4), (b) (6)	21 Nov 2020 15:15:12

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:51:21

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:36:16
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	20 Nov 2020 02:07:51
	(b) (4)	
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

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:51:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:36:16
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
User entered 'Yes (Y)'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:51:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:36:16
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
User entered 'No (N)'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:51:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:36:16
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
User entered 'No (N)'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:51:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:36:16
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
User entered '18 Nov 2020'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:51:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:36:16
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
User entered empty.	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:51:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered empty.	System	20 Nov 2020 02:06:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:51:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:36:16
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
User entered 'No (N)' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	15 Dec 2020 18:14:16
User entered 'Yes (Y)'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:51:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:36:16
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	15 Dec 2020 18:14:16
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	15 Dec 2020 18:14:16
User entered '30 Nov 2020' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	15 Dec 2020 18:14:16
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	01 Dec 2020 19:18:16
User entered empty.	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:51:21

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:36:16
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
User entered empty.	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:51:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered empty.	System	20 Nov 2020 02:06:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:51:21

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:36:16
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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: 10 Jun 2021 09:51:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:36:16
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
User entered 'Yes (Y)'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

US3812059

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:51:21

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:36:16
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
User entered '0'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:51:21

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:36:16
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
User entered '0'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:51:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:36:16
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
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)	04 Dec 2020 10:03:44
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Updated' (Site from System).	Angie Kean (b) (4)	01 Dec 2020 18:53:49
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	01 Dec 2020 18:48:39
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

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:51:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '1'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:51:21

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:36:16
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
User entered '18 Nov 2020' reason for change: Data Entry Error	Angie Kean (b) (4)	01 Dec 2020 19:18:16
	(b) (4)	
User entered '19 Nov 2020' reason for change: Data Entry Error	Angie Kean (b) (4)	01 Dec 2020 18:48:39
	(b) (4)	
User entered '18 Nov 2020'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:51:21

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:36:16
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
User entered '30 Nov 2020' reason for change: New Information	Angie Kean (b) (4)	01 Dec 2020 19:18:16
	(b) (4)	
User entered empty.	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

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Folder: Adverse Events

Form: Adverse Events (7)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:36:16
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
User entered 'No (N)'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:36:16
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
User entered empty.	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

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Folder: Adverse Events

Form: Adverse Events (7)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:36:16
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
User entered '0'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29
	(b) (4)	

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:36:16
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
User entered '0'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:36:16
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
User entered '0'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

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Folder: Adverse Events

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:36:16
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
User entered 'Not Related (NOT RELATED)'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:51:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:36:16
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
User entered 'Not Related (NOT RELATED)'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

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Folder: Adverse Events

Form: Adverse Events (7)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:36:16
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
User entered 'Not Applicable (NOT APPLICABLE)'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

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Folder: Adverse Events

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:36:16
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
User entered '0'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

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Folder: Adverse Events

Form: Adverse Events (7)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:36:16
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed recorded was given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify. '(Site from DM).	(b) (4), (b) (6)	16 Dec 2020 21:08:20
Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed recorded was given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify. ' answered with 'updated' (Site from DM).	Lyly Dang (b) (4)	16 Dec 2020 17:57:13
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed recorded was given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify. '(Site from DM).	(b) (4), (b) (6)	14 Dec 2020 05:28:55
User entered '1'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

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Folder: Adverse Events

Form: Adverse Events (7)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 22:30:21
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Un-verified.	Lyly Dang (b) (4)	28 Apr 2021 18:51:48
Signature has been broken.	Lyly Dang (b) (4)	28 Apr 2021 18:51:48
User entered '1' reason for change: Data Entry Error	Lyly Dang (b) (4)	28 Apr 2021 18:51:48
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:36:16
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
User entered '0'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

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Folder: Adverse Events

Form: Adverse Events (7)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:36:16
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	15 Dec 2020 18:14:16
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	Angie Kean (b) (4)	01 Dec 2020 19:18:16
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

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Form: Adverse Events (7)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:36:16
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	15 Dec 2020 18:14:16
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	01 Dec 2020 19:18:16
User entered empty.	Lyly Dang (b) (4)	20 Nov 2020 02:06:29

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:36:16
User signature succeeded.	Lyly Dang (b) (4)	12 Mar 2021 21:48:25
User closed query 'Per DM CLR: SAE Narrative = SUBSTANCE USE TREATMENT PROGRAM. Please review and verify if this should be recorded in the ConProc eCRF. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 17:21:09
User closed query 'Per DM CLR: SAE Narrative = ORDER TO DISCONTINUE BUPROPION HCL 150 MG DAILY. However, this medication is still ongoing in the CM eCRF. Please review and verify if the data should be reconciled. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 15:11:15
User closed query 'Per DM CLR: SAE Narrative = POSITIVE URINE DRUG SCREEN FOR CANNABINOIDS. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 14:10:09
Query 'Per DM CLR: SAE Narrative = SUBSTANCE USE TREATMENT PROGRAM. Please review and verify if this should be recorded in the ConProc eCRF. ' answered with 'ok' (Site from DM).	lauren clement (b) (4)	08 Mar 2021 19:44:31
Query 'Per DM CLR: SAE Narrative = ORDER TO DISCONTINUE BUPROPION HCL 150 MG DAILY. However, this medication is still ongoing in the CM eCRF. Please review and verify if the data should be reconciled. ' answered with 'ok' (Site from DM).	lauren clement (b) (4)	08 Mar 2021 19:41:18
Query 'Per DM CLR: SAE Narrative = POSITIVE URINE DRUG SCREEN FOR CANNABINOIDS. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'sure' (Site from DM).	lauren clement (b) (4)	08 Mar 2021 19:40:15

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Form: Adverse Events (7)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = SUBSTANCE USE TREATMENT PROGRAM. Please review and verify if this should be recorded in the ConProc eCRF. ' (Site from DM).	(b) (4), (b) (6)	17 Jan 2021 23:53:38
User opened query 'Per DM CLR: SAE Narrative = ORDER TO DISCONTINUE BUPROPION HCL 150 MG DAILY. However, this medication is still ongoing in the CM eCRF. Please review and verify if the data should be reconciled. ' (Site from DM).	(b) (4), (b) (6)	17 Jan 2021 23:53:30
User opened query 'Per DM CLR: SAE Narrative = POSITIVE URINE DRUG SCREEN FOR CANNABINOIDS. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	17 Jan 2021 23:53:23
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 15:17:16
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'Updated' (Site from Safety).	Lyly Dang (b) (4)	16 Dec 2020 17:57:37

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'This subject is a 21-year-old female who was hospitalized on 18 Nov 2020 with an admitting diagnosis of "major depressive disorder recurrent." This subject has a past medical history of anxiety, depression, post-traumatic stress disorder, alcohol abuse, and cannabis abuse. The subject had two prior hospitalizations this past year due to her anxiety disorder and major depressive disorder. Prior to this hospitalization, the subject was attending an intensive outpatient behavioral health program 3 days/week until it was recommended that inpatient therapy would be better suited for the subject at that time. Subject was subsequently admitted to the hospital on 18 Nov 2020 for a duration of 12 days. Per medical records, the subject received lorazepam 1 mg, olanzapine 10mg, quetiapine 400 mg, trazadone 100 mg, and hydroxyzine 50 mg during her hospitalization. Pertinent labs include a negative COVID-19 PCR and positive urine drug screen for cannabinoids. The subject was discharged in stable condition on 30 Nov 2020 with the order to discontinue bupropion HCL 150 mg daily and to start Latuda 40 mg daily, clonazepam 0.5 mg BID, and brimonidine 0.2% BID. The subject's final discharge diagnosis was "severe episode of recurrent major depressive disorder, without psychotic features." The subject was taken to a substance use treatment program in Arizona the same day of discharge.'	Lyly Dang (b) (4) [REDACTED] [REDACTED]	16 Dec 2020 17:57:30
reason for change: Data Entry Error User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6) [REDACTED]	09 Dec 2020 18:16:24

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[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

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '1'	System	20 Nov 2020 02:06:29

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Folder: Adverse Events

Form: Adverse Events (7)

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Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '1'	System	20 Nov 2020 02:06:29

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Folder: Adverse Events

Form: Adverse Events (7)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '0'	System	20 Nov 2020 02:06:29

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Folder: Adverse Events

Form: Adverse Events (8)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

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[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: Suspected COVID-19, LLT: Suspected COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 May 2021 18:45:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 May 2021 18:45:46
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Apr 2021 21:42:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Apr 2021 21:42:22
Data point term sent to Coder	System	29 Apr 2021 17:05:22
User entered 'covid-like illness'	Breanna Galibert (b) (4) (b) (4)	29 Apr 2021 17:05:07

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	29 Apr 2021 17:05:07
	(b) (4)	

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
User entered 'No (N)'	Breanna Galibert (b) (4)	29 Apr 2021 17:05:07
	(b) (4)	

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
User entered 'No (N)'	Breanna Galibert (b) (4)	29 Apr 2021 17:05:07
	(b) (4)	

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
User entered '08 Oct 2020'	Breanna Galibert (b) (4)	29 Apr 2021 17:05:07
	(b) (4)	

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Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
User entered empty.	Breanna Galibert (b) (4)	29 Apr 2021 17:05:07
	(b) (4)	

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Folder: Adverse Events

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered empty.	System	29 Apr 2021 17:05:07

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
User entered 'No (N)'	Breanna Galibert (b) (4)	29 Apr 2021 17:05:07
	(b) (4)	

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
User entered '13 Oct 2020'	Breanna Galibert (b) (4)	29 Apr 2021 17:05:07
	(b) (4)	

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End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
User entered empty.	Breanna Galibert (b) (4)	29 Apr 2021 17:05:07
	(b) (4)	

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered empty.	System	29 Apr 2021 17:05:07

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Folder: Adverse Events

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Breanna Galibert (b) (4)	29 Apr 2021 17:05:07
	(b) (4)	

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
User entered 'No (N)'	Breanna Galibert (b) (4)	29 Apr 2021 17:05:07
	(b) (4)	

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
User entered '0'	Breanna Galibert (b) (4)	29 Apr 2021 17:05:07
	(b) (4)	

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
User entered '0'	Breanna Galibert (b) (4)	29 Apr 2021 17:05:07
	(b) (4)	

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
User entered '0'	Breanna Galibert (b) (4)	29 Apr 2021 17:05:07
	(b) (4)	

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
User entered empty.	Breanna Galibert (b) (4)	29 Apr 2021 17:05:07
	(b) (4)	

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
User entered empty.	Breanna Galibert (b) (4)	29 Apr 2021 17:05:07
	(b) (4)	

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
User entered empty.	Breanna Galibert (b) (4)	29 Apr 2021 17:05:07
	(b) (4)	

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
User entered empty.	Breanna Galibert (b) (4)	29 Apr 2021 17:05:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:51:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
User entered '0'	Breanna Galibert (b) (4)	29 Apr 2021 17:05:07
	(b) (4)	

US3812059

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:51:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
User entered '0'	Breanna Galibert (b) (4)	29 Apr 2021 17:05:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:51:21

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
User entered '0'	Breanna Galibert (b) (4)	29 Apr 2021 17:05:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:51:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4)	29 Apr 2021 17:05:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:51:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4)	29 Apr 2021 17:05:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:51:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
User entered 'Not Applicable (NOT APPLICABLE)'	Breanna Galibert (b) (4)	29 Apr 2021 17:05:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:51:21

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
User entered '0'	Breanna Galibert (b) (4)	29 Apr 2021 17:05:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:51:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
User entered '1'	Breanna Galibert (b) (4)	29 Apr 2021 17:05:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:51:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
User entered '0'	Breanna Galibert (b) (4)	29 Apr 2021 17:05:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:51:21

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Breanna Galibert (b) (4)	29 Apr 2021 17:05:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:51:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
User entered empty.	Breanna Galibert (b) (4)	29 Apr 2021 17:05:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:51:21

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
User entered empty.	Breanna Galibert (b) (4)	29 Apr 2021 17:05:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:51:21

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '0'	System	29 Apr 2021 17:05:07

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:51:21

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '1'	System	29 Apr 2021 17:05:07

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:51:21

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 13:33:25
User closed query 'Per ETRTR: Please add medications dosed at SAE "Reoccurrent Major Depressive Disorder" Hospitalization from 18Nov20 through 30Nov20, thanks.' (Site from CRA).	(b) (4), (b) (6)	27 Apr 2021 14:46:01
Query 'Per ETRTR: Please add medications dosed at SAE "Reoccurrent Major Depressive Disorder" Hospitalization from 18Nov20 through 30Nov20, thanks.' answered with 'MR reports "Administered Medication List" Although wording reports "Administered" Only some medications are time stamped to prove given. All other medications were ordered from treating physician, but not given. Therefore, only report medications with a timestamp. Conmed list correct. Thanks.' (Site from CRA).	lauren clement (b) (4)	08 Mar 2021 19:48:40
User opened query 'Per ETRTR: Please add medications dosed at SAE "Reoccurrent Major Depressive Disorder" Hospitalization from 18Nov20 through 30Nov20, thanks.' (Site from CRA).	(b) (4), (b) (6)	04 Dec 2020 23:02:10
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:21

[Name of Medication](#)

Audit	User	Time (GMT)
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
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User closed 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)	26 Nov 2020 10:44:56
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
Signature has been broken.	Lyly Dang (b) (4)	28 Apr 2021 23:04:36
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered '.135'	Heather Cherniawski	07 Aug 2020 14:02:47
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'mg (mg)'	Heather Cherniawski	07 Aug 2020 14:02:47
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
Signature has been broken.	lauren clement (b) (4)	29 Apr 2021 18:36:15
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Heather Cherniawski	07 Aug 2020 14:02:47
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'once daily (QD)'	Heather Cherniawski	07 Aug 2020 14:02:47
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
Signature has been broken.	Lyly Dang (b) (4)	28 Apr 2021 23:06:21
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Heather Cherniawski	07 Aug 2020 14:02:47
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'Vaginal (VAGINAL)'	Heather Cherniawski	07 Aug 2020 14:02:47
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:21

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Heather Cherniawski	07 Aug 2020 14:02:47
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Un-verified.	Breanna Galibert (b) (4)	29 Apr 2021 16:20:02
Signature has been broken.	Breanna Galibert (b) (4)	29 Apr 2021 16:20:02
User entered 'UN Jun 2020' reason for change: Data Entry Error	Breanna Galibert (b) (4)	29 Apr 2021 16:20:02
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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).	System	07 Aug 2020 14:02:47
User entered 'UN UNK 2020'	Heather Cherniawski (b) (4)	07 Aug 2020 14:02:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered '0'	Heather Cherniawski	07 Aug 2020 14:02:47
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'Yes (Y)'	Heather Cherniawski	07 Aug 2020 14:02:47
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Heather Cherniawski	07 Aug 2020 14:02:47
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Un-verified.	Breanna Galibert (b) (4)	29 Apr 2021 16:20:16
	(b) (4)	
Signature has been broken.	Breanna Galibert (b) (4)	29 Apr 2021 16:20:16
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Breanna Galibert (b) (4)	29 Apr 2021 16:20:16
	(b) (4)	
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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	Any Penly (b) (4)	08 Aug 2020 17:20:13
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 14:02:47
User entered empty.	Heather Cherniawski	07 Aug 2020 14:02:47
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '1'	System	07 Aug 2020 14:02:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '1'	System	07 Aug 2020 14:02:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '804 (804)'	System	07 Aug 2020 14:02:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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)	12 Mar 2021 07:14:41
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Mar 2021 07:14:41
	(b) (4)	
Data point term sent to Coder	System	08 Mar 2021 20:27:00
Data point term sent to Coder	System	08 Mar 2021 19:55:51
DataPoint Un-verified.	lauren clement (b) (4)	08 Mar 2021 19:55:05
Coding entries removed.	lauren clement (b) (4)	08 Mar 2021 19:55:05
User entered 'TRAVATAN 0.004%' reason for change: Per Query Resolution	lauren clement (b) (4)	08 Mar 2021 19:55:05
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)	03 Nov 2020 16:16:21
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Nov 2020 16:16:21
	(b) (4)	
Data point term sent to Coder	System	03 Nov 2020 16:16:09
Coding entries removed.	Angie Kean (b) (4)	03 Nov 2020 16:15:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:21

[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)	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)	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)	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)	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: 10 Jun 2021 09:51:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'No (N)'	Heather Cherniawski	07 Aug 2020 14:04:11
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'GLAUCOMA'	Heather Cherniawski	07 Aug 2020 14:04:11
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User closed query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=drop). Review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 13:36:37
Query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=drop). Review and amend as appropriate.' answered with 'OK' (Site from DM).	lauren clement (b) (4)	08 Mar 2021 19:55:11
DataPoint Un-verified.	lauren clement (b) (4)	08 Mar 2021 19:55:05
User entered '1' reason for change: Per Query Resolution	lauren clement (b) (4)	08 Mar 2021 19:55:05
User opened query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=drop). Review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 12:29:04
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: 10 Jun 2021 09:51:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Un-verified.	lauren clement (b) (4)	08 Mar 2021 19:55:05
User entered 'Other (OTHER)' reason for change: Per Query Resolution	lauren clement (b) (4)	08 Mar 2021 19:55:05
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'mL (mL)'	Heather Cherniawski	07 Aug 2020 14:04:11
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Un-verified.	lauren clement (b) (4)	08 Mar 2021 19:55:05
User entered 'DROP' reason for change: Per Query Resolution	lauren clement (b) (4)	08 Mar 2021 19:55:05
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Heather Cherniawski	07 Aug 2020 14:04:11
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'once daily (QD)'	Heather Cherniawski	07 Aug 2020 14:04:11
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Heather Cherniawski	07 Aug 2020 14:04:11
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
	(b) (4), (b) (6)	
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:14:40
	(b) (4), (b) (6)	
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
	(b) (4), (b) (6)	
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
	(b) (4)	
DataPoint Un-verified.	Angie Kean (b) (4)	03 Nov 2020 16:15:45
	(b) (4)	
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
	(b) (4), (b) (6)	
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
	(b) (4), (b) (6)	
User entered 'Intraocular (INTRAOCULAR)' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	07 Aug 2020 14:11:09
	(b) (4)	
User entered 'Other (OTHER)'	Heather Cherniawski	07 Aug 2020 14:04:11
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
Query 'Per DM RQ: Please review route as DROP is not a route but a unit. Update to change route to a more appropriate one (e.g. Ophthalmic). ' canceled (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 13:35:53
User closed query 'Per DM CLR: Please review route as DROP is not a route but a unit. Update to change route to a more appropriate one (e.g. Ophthalmic). ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 13:35:12
User opened query 'Per DM RQ: Please review route as DROP is not a route but a unit. Update to change route to a more appropriate one (e.g. Ophthalmic). ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 13:35:10
DataPoint Un-verified.	lauren clement (b) (4)	08 Mar 2021 20:26:30
User entered 'Ophthalmic' reason for change: Data Entry Error	lauren clement (b) (4)	08 Mar 2021 20:26:30
Query 'Per DM CLR: Please review route as DROP is not a route but a unit. Update to change route to a more appropriate one (e.g. Ophthalmic). ' answered with 'Your last query asked to add route as "drop", so leave it as drop' (Site from DM).	lauren clement (b) (4)	08 Mar 2021 19:55:39
User opened query 'Per DM CLR: Please review route as DROP is not a route but a unit. Update to change route to a more appropriate one (e.g. Ophthalmic). ' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 12:29:16
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	Angie Kean (b) (4)	03 Nov 2020 16:15:45
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty; reason for change Data Entry Error	Heather Cherniawski (b) (4)	07 Aug 2020 14:11:09

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered 'DROP'	Heather Cherniawski (b) (4)	07 Aug 2020 14:04:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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 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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered '0'	Heather Cherniawski	07 Aug 2020 14:04:11
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Angie Kean (b) (4)	14 Nov 2020 01:41:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'Yes (Y)'	Heather Cherniawski	07 Aug 2020 14:04:11
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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
	(b) (4)	
User entered '30 Oct 2020' reason for change: New Information	Angie Kean (b) (4)	14 Nov 2020 01:41:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Heather Cherniawski	07 Aug 2020 14:04:11
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 14:04:11
User entered empty.	Heather Cherniawski	07 Aug 2020 14:04:11
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '1'	System	07 Aug 2020 14:04:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '1'	System	07 Aug 2020 14:04:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '804 (804)'	System	07 Aug 2020 14:04:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:51:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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)	08 Apr 2021 20:54:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 20:54:54
Data point term sent to Coder Coding entries removed.	System Angie Kean (b) (4) (b) (4)	08 Apr 2021 15:02:15 08 Apr 2021 15:01:24
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)	15 Mar 2021 06:35:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 06:35:53
Data point term sent to Coder DataPoint Un-verified.	System lauren clement (b) (4)	08 Mar 2021 19:58:54 08 Mar 2021 19:58:50
Coding entries removed.	lauren clement (b) (4)	08 Mar 2021 19:58:50
User entered 'COSOPT 6.8mg/mL' reason for change: Per Query Resolution	lauren clement (b) (4)	08 Mar 2021 19:58:50

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:51:21

[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)	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)	03 Nov 2020 16:31:21
Data point term sent to Coder Coding entries removed.	System	03 Nov 2020 16:16:09
	Angie Kean (b) (4)	03 Nov 2020 16:16:04
DataPoint Verified.	(b) (4)	
	(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)	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)	07 Aug 2020 14:08:10
Data point term sent to Coder	System	07 Aug 2020 14:07:21
User entered 'COSOPT'	Heather Cherniawski (b) (4)	07 Aug 2020 14:06:37

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:51:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'No (N)'	Heather Cherniawski	07 Aug 2020 14:06:37
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:51:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'GLAUCOMA'	Heather Cherniawski	07 Aug 2020 14:06:37
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:51:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User closed query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=drop). Review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 14:10:21
DataPoint Un-verified.	lauren clement (b) (4)	08 Mar 2021 19:58:50
User entered '1' reason for change: Per Query Resolution	lauren clement (b) (4)	08 Mar 2021 19:58:50
Query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=drop). Review and amend as appropriate.' answered with 'ok' (Site from DM).	lauren clement (b) (4)	08 Mar 2021 19:57:51
User opened query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=drop). Review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 12:22:19
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: 10 Jun 2021 09:51:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Un-verified.	lauren clement (b) (4)	08 Mar 2021 19:58:50
User entered 'Other (OTHER)' reason for change: Per Query Resolution	lauren clement (b) (4)	08 Mar 2021 19:58:50
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'mL (mL)'	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: 10 Jun 2021 09:51:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User closed query 'Per DM CLR: Please review route, as this is not the expected route for this medication. Please verify if OPTHALMIC would be more appropriate route for this type of medication. If so, review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 18:45:54
Query 'Per DM CLR: Please review route, as this is not the expected route for this medication. Please verify if OPTHALMIC would be more appropriate route for this type of medication. If so, review and update as appropriate. ' answered with 'updated' (Site from DM).	Angie Kean (b) (4)	08 Apr 2021 15:01:40
User entered 'drop' reason for change: Data Entry Error	(b) (4)	08 Apr 2021 15:01:24
User entered 'ophthalmic' reason for change: Per Query Resolution	Angie Kean (b) (4)	08 Apr 2021 15:00:55
User opened query 'Per DM CLR: Please review route, as this is not the expected route for this medication. Please verify if OPTHALMIC would be more appropriate route for this type of medication. If so, review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 09:48:53
DataPoint Un-verified.	lauren clement (b) (4)	08 Mar 2021 19:58:50
User entered 'drop' reason for change: Data Entry Error	lauren clement (b) (4)	08 Mar 2021 19:58:50
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	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: 10 Jun 2021 09:51:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'twice daily (BID)'	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: 10 Jun 2021 09:51:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	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: 10 Jun 2021 09:51:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
	(b) (4), (b) (6)	
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:15:26
	(b) (4), (b) (6)	
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
	(b) (4), (b) (6)	
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
	(b) (4)	
DataPoint Un-verified.	Angie Kean (b) (4)	03 Nov 2020 16:16:04
	(b) (4)	
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
	(b) (4), (b) (6)	
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
	(b) (4), (b) (6)	
User entered 'Intraocular (INTRAOCULAR)'	Heather Cherniawski	07 Aug 2020 14:06:37
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:51:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
	(b) (4)	
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
	(b) (4)	
DataPoint Un-verified.	Angie Kean (b) (4)	08 Apr 2021 15:01:24
	(b) (4)	
User entered 'ophthalmic' reason for change: New Information	Angie Kean (b) (4)	08 Apr 2021 15:01:24
	(b) (4)	
User closed query 'Per DM CLR: Please review route as DROP is not a route but a unit. Update to change route to a more appropriate one (e.g. Ophthalmic). ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 14:24:29
	(b) (4)	
Query 'Per DM CLR: Please review route as DROP islauren clement not a route but a unit. Update to change route to a more appropriate one (e.g. Ophthalmic). ' answered with 'Per last query you requested drop, so leave it as drop' (Site from DM).	(b) (4)	08 Mar 2021 19:58:45
	(b) (4), (b) (6)	
User opened query 'Per DM CLR: Please review route as DROP is not a route but a unit. Update to change route to a more appropriate one (e.g. Ophthalmic). ' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 12:23:51
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 02:15:28
	(b) (4)	
DataPoint Un-verified.	Angie Kean (b) (4)	03 Nov 2020 16:16:04
	(b) (4)	
User entered 'DROP' reason for change: Data Entry Error	Angie Kean (b) (4)	03 Nov 2020 16:16:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
	(b) (4)	
User entered empty.	Heather Cherniawski	07 Aug 2020 14:06:37
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:51:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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
	(b) (4)	
User entered '01 May 2018' reason for change: Per Query Resolution	Karen Knapp (b) (4)	10 Nov 2020 18:16:13
	(b) (4)	
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 19:59:26
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
	(b) (4)	
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 14:06:37
User entered '1 May 2018'	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: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered '0'	Heather Cherniawski	07 Aug 2020 14:06:37
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:51:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'Yes (Y)'	Heather Cherniawski	07 Aug 2020 14:06:37
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:51:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	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: 10 Jun 2021 09:51:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 14:06:37
User entered empty.	Heather Cherniawski	07 Aug 2020 14:06:37
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:51:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '1'	System	07 Aug 2020 14:06:37

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:51:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:51:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'No (N)'	Heather Cherniawski	07 Aug 2020 14:09:58
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:51:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered '100'	Heather Cherniawski	07 Aug 2020 14:09:58
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:51:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Heather Cherniawski	07 Aug 2020 14:09:58
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:51:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'once daily (QD)'	Heather Cherniawski	07 Aug 2020 14:09:58
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:51:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Heather Cherniawski	07 Aug 2020 14:09:58
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:51:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'Oral (ORAL)'	Heather Cherniawski	07 Aug 2020 14:09:58
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:51:21

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered empty.	Heather Cherniawski	07 Aug 2020 14:09:58
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:51:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered '0'	Heather Cherniawski	07 Aug 2020 14:09:58
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:51:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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	07 Aug 2020 14:09:58
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:51:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 14:09:58
User entered empty.	Heather Cherniawski	07 Aug 2020 14:09:58
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:51:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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
	(b) (4)	
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
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:51:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:51:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:51:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:51:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:51:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:51:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered empty.	System	28 Oct 2020 23:13:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:51:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered empty.	System	28 Oct 2020 23:13:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:51:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered empty.	System	28 Oct 2020 23:13:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:51:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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 Apr 2021 05:39:12
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Apr 2021 05:39:12
	(b) (4)	
Data point term sent to Coder	System	29 Apr 2021 16:23:34
Coding entries removed.	Breanna Galibert (b) (4)	29 Apr 2021 16:23:25
	(b) (4)	
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 22:44:03
	(b) (4)	
Data point term sent to Coder	System	30 Oct 2020 22:43:32
Coding entries removed.	Angie Kean (b) (4)	30 Oct 2020 22:42:47
	(b) (4)	
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)	29 Oct 2020 20:12:32
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 20:12:32
	(b) (4)	
Data point term sent to Coder	System	28 Oct 2020 23:17:56

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:51:21

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Nicotine patch'	Lyly Dang (b) (4)	28 Oct 2020 23:17:13

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:51:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:51:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Un-verified.	Breanna Galibert (b) (4)	29 Apr 2021 16:23:25
	(b) (4)	
Signature has been broken.	Breanna Galibert (b) (4)	29 Apr 2021 16:23:25
	(b) (4)	
User entered 'WORSENING NICOTINE ADDICTION' reason for change: Data Entry Error	Breanna Galibert (b) (4)	29 Apr 2021 16:23:25
	(b) (4)	
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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
	(b) (4)	
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 '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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:51:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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
	(b) (4)	
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 '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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:51:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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
	(b) (4)	
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:51:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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)	30 Oct 2020 22:42:55
	(b) (4)	
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:51:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Un-verified.	Breanna Galibert (b) (4)	29 Apr 2021 16:22:44
	(b) (4)	
Signature has been broken.	Breanna Galibert (b) (4)	29 Apr 2021 16:22:44
	(b) (4)	
User entered 'once daily (QD)' reason for change:	Breanna Galibert (b) (4)	29 Apr 2021 16:22:44
Data Entry Error	(b) (4)	
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 16:44:24
User entered 'once (ONCE)' reason for change: Data	Angie Kean (b) (4)	30 Oct 2020 22:42:47
Entry Error	(b) (4)	
User closed query 'Data is required. Please	System	28 Oct 2020 23:17:49
complete.' (Site from System).		
Query 'Data is required. Please complete.' answered	System	28 Oct 2020 23:17:49
by data change (Site from System).		
User entered 'unknown (UNKNOWN)' reason for	Lyly Dang (b) (4)	28 Oct 2020 23:17:49
change: Data Entry Error		
User opened query 'Data is required. Please	System	28 Oct 2020 23:17:13
complete.' (Site from System).		
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: 10 Jun 2021 09:51:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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)	30 Oct 2020 22:42:07
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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
	(b) (4)	
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: 10 Jun 2021 09:51:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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)	30 Oct 2020 22:42:07
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '1'	System	29 Apr 2021 16:22:44
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: 10 Jun 2021 09:51:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '1'	System	29 Apr 2021 16:22:44
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: 10 Jun 2021 09:51:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '804 (804)'	System	29 Apr 2021 16:22:44
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: 10 Jun 2021 09:51:21

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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)	30 Apr 2021 05:39:12
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Apr 2021 05:39:12
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
Data point term sent to Coder DataPoint Un-verified.	System	29 Apr 2021 16:23:34
	Breanna Galibert (b) (4)	29 Apr 2021 16:23:03
	(b) (4)	
Coding entries removed.	Breanna Galibert (b) (4)	29 Apr 2021 16:23:03
	(b) (4)	
Signature has been broken.	Breanna Galibert (b) (4)	29 Apr 2021 16:23:03
	(b) (4)	
User entered 'NICOTINE POLAINLEX GUM' reason for change: Data Entry Error	Breanna Galibert (b) (4)	29 Apr 2021 16:23:03
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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)	01 Nov 2020 03:25:45
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Nov 2020 03:25:45
	(b) (4)	
Data point term sent to Coder	System	01 Nov 2020 01:18:45
User entered 'Nicotine gum'	Lyly Dang (b) (4)	01 Nov 2020 01:18:30

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:51:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Un-verified.	Breanna Galibert (b) (4)	29 Apr 2021 16:23:12
	(b) (4)	
Signature has been broken.	Breanna Galibert (b) (4)	29 Apr 2021 16:23:12
	(b) (4)	
User entered 'WORSENING NICOTINE ADDICTION' reason for change: Data Entry Error	Breanna Galibert (b) (4)	29 Apr 2021 16:23:12
	(b) (4)	
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:51:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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)	01 Nov 2020 01:20:44

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:51:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history of GLAUCOMA worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 20:09:01
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 22:32:10
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history of GLAUCOMA worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' answered with 'progress note dated 27 Aug 2020 notes that the subject denied worsening of glaucoma ' (Site from DM).	Lyly Dang (b) (4)	28 Apr 2021 19:10:20
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history of GLAUCOMA worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 09:49:27
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening GLAUCOMA should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 14:25:50

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:51:21

Name of Medication

Audit	User	Time (GMT)
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)	08 Mar 2021 23:19:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 23:19:55
Data point term sent to Coder	System	08 Mar 2021 20:28:01
Data point term sent to Coder	System	08 Mar 2021 20:13:27
DataPoint Un-verified.	lauren clement (b) (4) (b) (4) (b) (4)	08 Mar 2021 20:13:26
User entered 'ALPHAGAN 0.05%' reason for change: Data Entry Error	lauren clement (b) (4) (b) (4)	08 Mar 2021 20:13:26
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening GLAUCOMA should be recorded, and update con med indication or provide clarification. ' answered with 'Per MR review; providing physician states Glaucoma is stable, do not change term. Unsure of why medications were changed; but confirmed not do to worsening of disease. ' (Site from DM).	lauren clement (b) (4) (b) (4)	08 Mar 2021 20:12:42
Data point term sent to Coder	System	08 Mar 2021 20:12:25
Coding entries removed.	lauren clement (b) (4) (b) (4)	08 Mar 2021 20:11:46
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening GLAUCOMA should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	22 Jan 2021 12:17:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Nov 2020 16:44:24

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:51:21

[Name of Medication](#)

Audit	User	Time (GMT)
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) (b) (4)	01 Nov 2020 01:22:24

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:51:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 22:32:29
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User closed query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate.' (Site from DM). Query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate.' answered with 'OK' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 14:13:24
DataPoint Un-verified.	lauren clement (b) (4)	08 Mar 2021 20:13:33
User entered '1' reason for change: Per Query Resolution	lauren clement (b) (4)	08 Mar 2021 20:13:26
User opened query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 12:17:59
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: 10 Jun 2021 09:51:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 22:32:31
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Un-verified.	lauren clement (b) (4)	08 Mar 2021 20:13:26
User entered 'DROP' reason for change: Data Entry Error	lauren clement (b) (4)	08 Mar 2021 20:13:26
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:51:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:51:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User closed query 'Per DM Rq: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 20:10:12
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 22:32:41
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
Query 'Per DM Rq: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'Ophthalmic route is correct. What would be the suggested alternative to this route of administration' (Site from DM).	Lyly Dang (b) (4)	28 Apr 2021 19:19:55
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 14:13:55
User opened query 'Per DM Rq: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 14:13:52
User entered 'Other (OTHER)' reason for change: Per Query Resolution	lauren clement (b) (4)	08 Mar 2021 20:27:17
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'OK' (Site from DM).	lauren clement (b) (4)	08 Mar 2021 20:13:50
DataPoint Un-verified.	lauren clement (b) (4)	08 Mar 2021 20:11:46
User entered 'Topical (TOPICAL)' reason for change: Per Query Resolution	lauren clement (b) (4)	08 Mar 2021 20:11:46
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 12:18:27

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:51:21

[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: 10 Jun 2021 09:51:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 22:32:42
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Un-verified.	lauren clement (b) (4)	08 Mar 2021 20:27:17
User entered 'ophthalmic' reason for change: Data Entry Error	lauren clement (b) (4)	08 Mar 2021 20:27:17
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Angie Kean (b) (4)	14 Nov 2020 01:42:38
	(b) (4)	
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: 10 Jun 2021 09:51:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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
	(b) (4)	
User entered '30 Oct 2020' reason for change: New Information	Angie Kean (b) (4)	14 Nov 2020 01:42:38
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User closed query 'Per DM RQ: Please review the start/stop date of this medication as it overlaps with Con Med#12 BUPROPRIION ER (31Oct2020-ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	01 May 2021 10:14:06
	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
Query 'Per DM RQ: Please review the start/stop date of this medication as it overlaps with Con Med#12 BUPROPRIION ER (31Oct2020-ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' answered with 'data is correct. Subject took BUPROPRIION ER 150 mg from 27 Oct 2020 to 30 Oct 2020 for anxiety disorder; Subject then took BUPROPRIION ER 150 mg from 31 Oct 2020 to 30 Nov 2020 for a different indication of major depressive disorder ' (Site from DM).	Lyly Dang (b) (4)	28 Apr 2021 19:06:30
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med#12 BUPROPRIION ER (31Oct2020-ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 14:14:54
User opened query 'Per DM RQ: Please review the start/stop date of this medication as it overlaps with Con Med#12 BUPROPRIION ER (31Oct2020-ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 14:14:52
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med#12 BUPROPRIION ER (31Oct2020-ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' answered with 'ok' (Site from DM).	lauren clement (b) (4)	08 Mar 2021 19:45:43

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:51:21

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med#12 BUPROPION ER (31Oct2020-ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 12:20:12
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.	Coder Import (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: 10 Jun 2021 09:51:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:51:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:51:21

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:51:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:51:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:24:26
Signature has been broken.	Breanna Galibert (b) (4)	29 Apr 2021 16:26:32
	(b) (4)	
User entered 'Yes (Y)' reason for change: Per Query Resolution	Breanna Galibert (b) (4)	29 Apr 2021 16:26:32
	(b) (4)	
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Un-verified.	lauren clement (b) (4)	08 Mar 2021 19:46:08
User entered 'No (N)' reason for change: Per Query Resolution	lauren clement (b) (4)	08 Mar 2021 19:46:08
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:51:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:24:28
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	29 Apr 2021 16:26:32
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	29 Apr 2021 16:26:24
Signature has been broken.	Breanna Galibert (b) (4)	29 Apr 2021 16:26:24
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Breanna Galibert (b) (4)	29 Apr 2021 16:26:24
	(b) (4)	
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Un-verified.	lauren clement (b) (4)	08 Mar 2021 19:46:08
User entered '30 Oct 2020' reason for change: Per Query Resolution	lauren clement (b) (4)	08 Mar 2021 19:46:08
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:51:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:51:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Apr 2021 20:41:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Apr 2021 20:41:08
Data point term sent to Coder	System	29 Apr 2021 16:32:45
Coding entries removed.	Breanna Galibert (b) (4) (b) (4)	29 Apr 2021 16:32:24
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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-STERIODS, 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)	01 Nov 2020 01:25:41

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:51:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:51:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Un-verified.	Breanna Galibert (b) (4)	29 Apr 2021 16:32:24
Signature has been broken.	Breanna Galibert (b) (4)	29 Apr 2021 16:32:24
User entered 'COVID-LIKE ILLNESS' reason for change: New Information	Breanna Galibert (b) (4)	29 Apr 2021 16:32:24
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User closed query 'Per DM CLR: Please note that there is no AE (SORE THROAT and MYALGIA) that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 14:27:47
Query 'Per DM CLR: Please note that there is no AE (SORE THROAT and MYALGIA) that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'these symptoms are captured in illness visit' (Site from DM).	lauren clement (b) (4)	08 Mar 2021 20:15:30
User opened query 'Per DM CLR: Please note that there is no AE (SORE THROAT and MYALGIA) that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 12:27:47
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:51:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:51:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:51:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not within the 7 day post IP admin. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 13:33:37
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not within the 7 day post IP admin. Update as appropriate. Otherwise, provide clarification.' answered with 'No, during illness visit. Changed' (Site from DM).	lauren clement (b) (4)	08 Mar 2021 20:16:00
DataPoint Un-verified.	lauren clement (b) (4)	08 Mar 2021 20:15:42
User entered 'No (N)' reason for change: Data Entry Error	lauren clement (b) (4)	08 Mar 2021 20:15:42
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not within the 7 day post IP admin. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 12:28:08
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: 10 Jun 2021 09:51:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '804 (804)'	System	01 Nov 2020 01:25:41

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:51:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	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: 10 Jun 2021 09:51:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Major Depressive Disorder'	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: 10 Jun 2021 09:51:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '100'	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: 10 Jun 2021 09:51:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'mg (mg)'	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: 10 Jun 2021 09:51:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:07:10
DataPoint Un-verified.	Anya Penly (b) (4)	21 Nov 2020 00:05:49
	(b) (4)	
User entered 'other (OTHER)' 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 '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: 10 Jun 2021 09:51:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:07:11
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: 10 Jun 2021 09:51:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Oral (ORAL)'	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: 10 Jun 2021 09:51:21

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '06 Nov 2020'	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: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '0'	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: 10 Jun 2021 09:51:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Yes (Y)'	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: 10 Jun 2021 09:51:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	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: 10 Jun 2021 09:51:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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)	14 Nov 2020 05:53:44
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 05:53:44
	(b) (4)	
Data point term sent to Coder	System	14 Nov 2020 01:35:16
User entered 'Clonazepam'	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: 10 Jun 2021 09:51:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	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: 10 Jun 2021 09:51:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Major Depressive Disorder'	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: 10 Jun 2021 09:51:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '0.5'	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: 10 Jun 2021 09:51:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'mg (mg)'	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: 10 Jun 2021 09:51:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	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: 10 Jun 2021 09:51:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:07:32
DataPoint Un-verified.	Anya Penly (b) (4)	21 Nov 2020 00:04:25
	(b) (4)	
User entered 'other (OTHER)' reason for change:	Anya Penly (b) (4)	21 Nov 2020 00:04:25
Data Entry Error	(b) (4)	
DataPoint Verified.	(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: 10 Jun 2021 09:51:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:07:34
DataPoint Un-verified.	Anya Penly (b) (4)	21 Nov 2020 00:04:25
	(b) (4)	
User entered 'TID PRN' reason for change: Data Entry Error	Anya Penly (b) (4)	21 Nov 2020 00:04:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4)	14 Nov 2020 01:35:07
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:51:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Oral (ORAL)'	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: 10 Jun 2021 09:51:21

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	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: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '30 Oct 2020'	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: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '0'	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: 10 Jun 2021 09:51:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Yes (Y)'	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: 10 Jun 2021 09:51:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	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: 10 Jun 2021 09:51:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	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: 10 Jun 2021 09:51:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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)	30 Apr 2021 04:32:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 04:32:19
Data point term sent to Coder	System	29 Apr 2021 16:51:11
Coding entries removed.	Breanna Galibert (b) (4) (b) (4)	29 Apr 2021 16:51:07
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	Angie Kean (b) (4)	14 Nov 2020 01:35:44
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:51:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Major Depressive Disorder'	Angie Kean (b) (4)	14 Nov 2020 01:35:44
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:51:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '50'	Angie Kean (b) (4)	14 Nov 2020 01:35:44
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:51:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'mg (mg)'	Angie Kean (b) (4)	14 Nov 2020 01:35:44
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:51:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4)	14 Nov 2020 01:35:44
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:51:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'as needed (PRN)'	Angie Kean (b) (4)	14 Nov 2020 01:35:44
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:51:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4)	14 Nov 2020 01:35:44
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:51:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:27:29
DataPoint Un-verified.	Breanna Galibert (b) (4)	29 Apr 2021 16:51:07
	(b) (4)	
Signature has been broken.	Breanna Galibert (b) (4)	29 Apr 2021 16:51:07
	(b) (4)	
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Breanna Galibert (b) (4)	29 Apr 2021 16:51:07
	(b) (4)	
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Topical (TOPICAL)'	Angie Kean (b) (4)	14 Nov 2020 01:35:44
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:51:21

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4)	14 Nov 2020 01:35:44
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '31 Oct 2020'	Angie Kean (b) (4)	14 Nov 2020 01:35:44
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '0'	Angie Kean (b) (4)	14 Nov 2020 01:35:44
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:51:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Yes (Y)'	Angie Kean (b) (4)	14 Nov 2020 01:35:44
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:51:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4)	14 Nov 2020 01:35:44
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:51:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	Angie Kean (b) (4)	14 Nov 2020 01:35:44
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:51:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	Angie Kean (b) (4)	14 Nov 2020 01:36:34
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:51:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Major Depressive Disorder'	Angie Kean (b) (4)	14 Nov 2020 01:36:34
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:51:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '2'	Angie Kean (b) (4)	14 Nov 2020 01:36:34
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:51:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'mg (mg)'	Angie Kean (b) (4)	14 Nov 2020 01:36:34
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:51:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4)	14 Nov 2020 01:36:34
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:51:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'once daily (QD)'	Angie Kean (b) (4)	14 Nov 2020 01:36:34
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:51:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4)	14 Nov 2020 01:36:34
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:51:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Oral (ORAL)'	Angie Kean (b) (4)	14 Nov 2020 01:36:34
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:51:21

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4)	14 Nov 2020 01:36:34
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '31 Oct 2020'	Angie Kean (b) (4)	14 Nov 2020 01:36:34
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '0'	Angie Kean (b) (4)	14 Nov 2020 01:36:34
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:51:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Yes (Y)'	Angie Kean (b) (4)	14 Nov 2020 01:36:34
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:51:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4)	14 Nov 2020 01:36:34
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:51:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	Angie Kean (b) (4)	14 Nov 2020 01:36:34
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:51:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	Angie Kean (b) (4)	14 Nov 2020 01:37:32
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:51:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Major Depressive Disorder'	Angie Kean (b) (4)	14 Nov 2020 01:37:32
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:51:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '300'	Angie Kean (b) (4)	14 Nov 2020 01:37:32
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:51:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'mg (mg)'	Angie Kean (b) (4)	14 Nov 2020 01:37:32
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:51:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4)	14 Nov 2020 01:37:32
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:51:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'other (OTHER)'	Angie Kean (b) (4)	14 Nov 2020 01:37:32
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:51:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User closed query 'Per CDM: Per page 54 of CCGs v5.0, Select the frequency using the drop-down list provided. If the frequency is not available from the list of choices, select 'Other', and specify in the text box provided. However the frequency indicated in the other specify is one of the available option "once daily" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).	(b) (4), (b) (6)	01 May 2021 10:14:53
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
Query 'Per CDM: Per page 54 of CCGs v5.0, Select the frequency using the drop-down list provided. If the frequency is not available from the list of choices, select 'Other', and specify in the text box provided. However the frequency indicated in the other specify is one of the available option "once daily" from the drop down list. Please update accordingly. Else Clarify. ' answered with 'No option from drop down list to specify subject takes medication every night. Please leave as is ' (Site from DM).	Lyly Dang (b) (4)	28 Apr 2021 19:37:36
User opened query 'Per CDM: Per page 54 of CCGs v5.0, Select the frequency using the drop-down list provided. If the frequency is not available from the list of choices, select 'Other', and specify in the text box provided. However the frequency indicated in the other specify is one of the available option "once daily" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 12:59:12
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: 10 Jun 2021 09:51:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Oral (ORAL)'	Angie Kean (b) (4)	14 Nov 2020 01:37:32
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:51:21

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4)	14 Nov 2020 01:37:32
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '31 Oct 2020'	Angie Kean (b) (4)	14 Nov 2020 01:37:32
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '0'	Angie Kean (b) (4)	14 Nov 2020 01:37:32
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:51:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:09:33
DataPoint Un-verified.	lauren clement (b) (4)	08 Mar 2021 20:33:50
User entered 'No (N)' reason for change: Data Entry Error	lauren clement (b) (4)	08 Mar 2021 20:33:50
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Yes (Y)'	Angie Kean (b) (4)	14 Nov 2020 01:37:32
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:51:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:09:35
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	08 Mar 2021 20:33:50
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	08 Mar 2021 20:33:39
DataPoint Un-verified.	lauren clement (b) (4)	08 Mar 2021 20:33:39
User entered '03 Nov 2020' reason for change: Data Entry Error	lauren clement (b) (4)	08 Mar 2021 20:33:39
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4)	14 Nov 2020 01:37:32
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:51:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	Angie Kean (b) (4)	14 Nov 2020 01:37:32
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:51:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med #17 QUETIAPINE (31Oct2020-ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 14:28:15
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med #17 QUETIAPINE (31Oct2020-ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' answered with 'OK' (Site from DM).	lauren clement (b) (4)	08 Mar 2021 20:32:55
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med #17 QUETIAPINE (31Oct2020-ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 12:28:36
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)	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)	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)	14 Nov 2020 01:38:01

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:51:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	Angie Kean (b) (4)	14 Nov 2020 01:38:01
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:51:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Major Depressive Disorder'	Angie Kean (b) (4)	14 Nov 2020 01:38:01
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:51:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:12:01
DataPoint Un-verified.	lauren clement (b) (4)	08 Mar 2021 20:33:11
User entered '325' reason for change: Data Entry Error	lauren clement (b) (4)	08 Mar 2021 20:33:11
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '25'	Angie Kean (b) (4)	14 Nov 2020 01:38:01
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:51:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'mg (mg)'	Angie Kean (b) (4)	14 Nov 2020 01:38:01
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:51:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4)	14 Nov 2020 01:38:01
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:51:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'once daily (QD)'	Angie Kean (b) (4)	14 Nov 2020 01:38:01
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:51:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4)	14 Nov 2020 01:38:01
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:51:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Oral (ORAL)'	Angie Kean (b) (4)	14 Nov 2020 01:38:01
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:51:21

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4)	14 Nov 2020 01:38:01
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '03 Nov 2020'	Angie Kean (b) (4)	14 Nov 2020 01:38:01
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '0'	Angie Kean (b) (4)	14 Nov 2020 01:38:01
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:51:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Yes (Y)'	Angie Kean (b) (4)	14 Nov 2020 01:38:01
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:51:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4)	14 Nov 2020 01:38:01
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:51:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	Angie Kean (b) (4)	14 Nov 2020 01:38:01
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:51:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	Angie Kean (b) (4)	14 Nov 2020 01:38:37
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:51:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Major Depressive Disorder'	Angie Kean (b) (4)	14 Nov 2020 01:38:37
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:51:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '100'	Angie Kean (b) (4)	14 Nov 2020 01:38:37
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:51:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'mg (mg)'	Angie Kean (b) (4)	14 Nov 2020 01:38:37
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:51:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4)	14 Nov 2020 01:38:37
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:51:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'as needed (PRN)'	Angie Kean (b) (4)	14 Nov 2020 01:38:37
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:51:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4)	14 Nov 2020 01:38:37
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:51:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Oral (ORAL)'	Angie Kean (b) (4)	14 Nov 2020 01:38:37
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:51:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4)	14 Nov 2020 01:38:37
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '30 Oct 2020'	Angie Kean (b) (4)	14 Nov 2020 01:38:37
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '0'	Angie Kean (b) (4)	14 Nov 2020 01:38:37
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:51:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Yes (Y)'	Angie Kean (b) (4)	14 Nov 2020 01:38:37
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:51:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4)	14 Nov 2020 01:38:37
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:51:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	Angie Kean (b) (4)	14 Nov 2020 01:38:37
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:51:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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)	08 Mar 2021 20:27:00
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Mar 2021 20:27:00
	(b) (4)	
Data point term sent to Coder	System	08 Mar 2021 20:25:42
DataPoint Un-verified.	lauren clement (b) (4)	08 Mar 2021 20:25:01
Coding entries removed.	lauren clement (b) (4)	08 Mar 2021 20:25:01
User entered 'LATANOPROST 0.005%' reason for change: Per Query Resolution	lauren clement (b) (4)	08 Mar 2021 20:25:01
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)	14 Nov 2020 01:40:37
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Nov 2020 01:40:37
	(b) (4)	
Data point term sent to Coder	System	14 Nov 2020 01:40:20
User entered 'Latanoprost'	Angie Kean (b) (4)	14 Nov 2020 01:40:13
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:51:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	Angie Kean (b) (4)	14 Nov 2020 01:40:13
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:51:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Glaucoma'	Angie Kean (b) (4)	14 Nov 2020 01:40:13
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:51:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User closed query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=drop). Review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 14:16:59
Query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=drop). Review and amend as appropriate.' answered with 'OK' (Site from DM).	lauren clement (b) (4)	08 Mar 2021 20:25:09
DataPoint Un-verified.	lauren clement (b) (4)	08 Mar 2021 20:25:01
User entered '1' reason for change: Per Query Resolution	lauren clement (b) (4)	08 Mar 2021 20:25:01
User opened query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=drop). Review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 12:27:00
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '0.005'	Angie Kean (b) (4)	14 Nov 2020 01:40:13

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:51:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Un-verified.	lauren clement (b) (4)	08 Mar 2021 20:25:01
User entered 'Other (OTHER)' reason for change: Per Query Resolution	lauren clement (b) (4)	08 Mar 2021 20:25:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'g (g)'	Angie Kean (b) (4)	14 Nov 2020 01:40:13
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:51:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Un-verified.	lauren clement (b) (4)	08 Mar 2021 20:25:01
User entered 'DROP' reason for change: Per Query Resolution	lauren clement (b) (4)	08 Mar 2021 20:25:01
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4)	14 Nov 2020 01:40:13
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:51:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'once daily (QD)'	Angie Kean (b) (4)	14 Nov 2020 01:40:13
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:51:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4)	14 Nov 2020 01:40:13
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:51:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User closed query 'Per DM CLR: Please review route as DROP is not a route but a unit. Update to change route to a more appropriate one (e.g. Ophthalmic). ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 17:23:45
Query 'Per DM CLR: Please review route as DROP islauren clement not a route but a unit. Update to change route to a more appropriate one (e.g. Ophthalmic). ' answered with 'ok' (Site from DM).	(b) (4)	08 Mar 2021 20:25:42
User entered 'Other (OTHER)' reason for change: Per Query Resolution	lauren clement (b) (4)	08 Mar 2021 20:25:35
DataPoint Un-verified.	lauren clement (b) (4)	08 Mar 2021 20:25:01
User entered 'Topical (TOPICAL)' reason for change: Per Query Resolution	lauren clement (b) (4)	08 Mar 2021 20:25:01
User opened query 'Per DM CLR: Please review route as DROP is not a route but a unit. Update to change route to a more appropriate one (e.g. Ophthalmic). ' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 12:27:15
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Intraocular (INTRAOCULAR)'	Angie Kean (b) (4)	14 Nov 2020 01:40:13
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:51:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Un-verified.	lauren clement (b) (4)	08 Mar 2021 20:25:35
User entered 'ophthalmic' reason for change: Per Query Resolution	lauren clement (b) (4)	08 Mar 2021 20:25:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4)	14 Nov 2020 01:40:13
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '31 Oct 2020'	Angie Kean (b) (4)	14 Nov 2020 01:40:13
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '0'	Angie Kean (b) (4)	14 Nov 2020 01:40:13
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:51:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Yes (Y)'	Angie Kean (b) (4)	14 Nov 2020 01:40:13
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:51:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4)	14 Nov 2020 01:40:13
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:51:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	Angie Kean (b) (4)	14 Nov 2020 01:40:13
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:51:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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)	29 Apr 2021 23:06:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Apr 2021 23:06:09
Data point term sent to Coder	System	29 Apr 2021 16:53:13
Coding entries removed.	Breanna Galibert (b) (4) (b) (4)	29 Apr 2021 16:53:04
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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: 10 Jun 2021 09:51:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	Angie Kean (b) (4)	14 Nov 2020 01:41:03
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:51:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Major Depressive Disorder'	Angie Kean (b) (4)	14 Nov 2020 01:41:03
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:51:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '50'	Angie Kean (b) (4)	14 Nov 2020 01:41:03
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:51:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'mg (mg)'	Angie Kean (b) (4)	14 Nov 2020 01:41:03
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:51:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4)	14 Nov 2020 01:41:03
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:51:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'once (ONCE)'	Angie Kean (b) (4)	14 Nov 2020 01:41:03
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:51:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4)	14 Nov 2020 01:41:03
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:51:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:31:13
DataPoint Un-verified.	Breanna Galibert (b) (4)	29 Apr 2021 16:53:04
	(b) (4)	
Signature has been broken.	Breanna Galibert (b) (4)	29 Apr 2021 16:53:04
	(b) (4)	
User entered 'Intramuscular (INTRAMUSCULAR)'	Breanna Galibert (b) (4)	29 Apr 2021 16:53:04
reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Intravenous (INTRAVENOUS)'	Angie Kean (b) (4)	14 Nov 2020 01:41:03
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:51:21

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4)	14 Nov 2020 01:41:03
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '30 Oct 2020'	Angie Kean (b) (4)	14 Nov 2020 01:41:03
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '0'	Angie Kean (b) (4)	14 Nov 2020 01:41:03
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:51:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	Angie Kean (b) (4)	14 Nov 2020 01:41:03
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:51:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '30 Oct 2020'	Angie Kean (b) (4)	14 Nov 2020 01:41:03
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:51:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	Angie Kean (b) (4)	14 Nov 2020 01:41:03
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:51:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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)	11 Mar 2021 16:51:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Mar 2021 16:51:50
Data point term sent to Coder	System	08 Mar 2021 20:30:02
Coding entries removed.	lauren clement (b) (4)	08 Mar 2021 20:29:08
DataPoint Un-verified.	lauren clement (b) (4)	08 Mar 2021 20:29:08
Coding entries removed.	lauren clement (b) (4)	08 Mar 2021 20:29:08
User entered 'DORZOLAMIDE-TIMOLOL 22.3mg/6.8mL' reason for change: Data Entry Error	lauren clement (b) (4)	08 Mar 2021 20:29:08
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: 10 Jun 2021 09:51:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	Angie Kean (b) (4)	14 Nov 2020 01:46:10
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:51:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Glaucoma'	Angie Kean (b) (4)	14 Nov 2020 01:46:10
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:51:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User closed query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=drop). Review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 14:35:59
Query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=drop). Review and amend as appropriate.' answered with 'ok' (Site from DM).	lauren clement (b) (4)	08 Mar 2021 20:29:14
DataPoint Un-verified.	lauren clement (b) (4)	08 Mar 2021 20:29:08
User entered '1' reason for change: Data Entry Error	lauren clement (b) (4)	08 Mar 2021 20:29:08
User opened query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=drop). Review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 12:25:29
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '22.3/6.8'	Angie Kean (b) (4)	14 Nov 2020 01:46:10

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:51:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Other (OTHER)'	Angie Kean (b) (4)	14 Nov 2020 01:46:10
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:51:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Un-verified.	lauren clement (b) (4)	08 Mar 2021 20:29:08
User entered 'drop' reason for change: Data Entry Error	lauren clement (b) (4)	08 Mar 2021 20:29:08
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'mg/mL'	Angie Kean (b) (4)	14 Nov 2020 01:46:10
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:51:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'twice daily (BID)'	Angie Kean (b) (4)	14 Nov 2020 01:46:10
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:51:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4)	14 Nov 2020 01:46:10
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:51:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
	(b) (4), (b) (6)	
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Please review route as DROP is not a route but a unit. Update to change route to a more appropriate one (e.g. Ophthalmic). ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 14:36:04
Query 'Per DM CLR: Please review route as DROP is not a route but a unit. Update to change route to a more appropriate one (e.g. Ophthalmic). ' answered with 'ok' (Site from DM).	lauren clement (b) (4)	08 Mar 2021 20:29:18
DataPoint Un-verified.	lauren clement (b) (4)	08 Mar 2021 20:29:08
User entered 'Other (OTHER)' reason for change: Data Entry Error	lauren clement (b) (4)	08 Mar 2021 20:29:08
User opened query 'Per DM CLR: Please review route as DROP is not a route but a unit. Update to change route to a more appropriate one (e.g. Ophthalmic). ' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 12:25:41
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Intraocular (INTRAOCULAR)'	Angie Kean (b) (4)	14 Nov 2020 01:46:10
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:51:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Un-verified.	lauren clement (b) (4)	08 Mar 2021 20:29:08
User entered 'ophthalmic' reason for change: Data Entry Error	lauren clement (b) (4)	08 Mar 2021 20:29:08
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4)	14 Nov 2020 01:46:10
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '01 Nov 2020'	Angie Kean (b) (4)	14 Nov 2020 01:46:10
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered '0'	Angie Kean (b) (4)	14 Nov 2020 01:46:10
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:51:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'Yes (Y)'	Angie Kean (b) (4)	14 Nov 2020 01:46:10
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:51:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered empty.	Angie Kean (b) (4)	14 Nov 2020 01:46:10
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:51:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:28:21
User entered 'No (N)'	Angie Kean (b) (4)	14 Nov 2020 01:46:10
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:51:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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)	21 Nov 2020 09:04:59
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Nov 2020 09:04:59
	(b) (4)	
Data point term sent to Coder	System	21 Nov 2020 00:23:18
User entered 'nicotine polacrilex lozenge'	Any Penly (b) (4)	21 Nov 2020 00:22:36
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:51:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered 'No (N)'	Anya Penly (b) (4)	21 Nov 2020 00:22:36
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:51:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered 'nicotine addiction'	Anya Penly (b) (4)	21 Nov 2020 00:22:36
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:51:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered '2'	Anya Penly (b) (4)	21 Nov 2020 00:22:36
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:51:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered 'mg (mg)'	Anya Penly (b) (4)	21 Nov 2020 00:22:36
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:51:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered empty.	Anya Penly (b) (4)	21 Nov 2020 00:22:36
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:51:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered 'other (OTHER)'	Anya Penly (b) (4)	21 Nov 2020 00:22:36
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:51:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered 'Q2hrs PRN'	Anya Penly (b) (4)	21 Nov 2020 00:22:36
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:51:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered 'Oral (ORAL)'	Anya Penly (b) (4)	21 Nov 2020 00:22:36
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:51:21

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered empty.	Anya Penly (b) (4)	21 Nov 2020 00:22:36
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered '31 Oct 2020'	Anya Penly (b) (4)	21 Nov 2020 00:22:36
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered '0'	Anya Penly (b) (4)	21 Nov 2020 00:22:36
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:51:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered 'No (N)'	Anya Penly (b) (4)	21 Nov 2020 00:22:36
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:51:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered '8 Nov 2020'	Anya Penly (b) (4)	21 Nov 2020 00:22:36
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:51:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered 'No (N)'	Anya Penly (b) (4)	21 Nov 2020 00:22:36
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:51:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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: 10 Jun 2021 09:51:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered empty.	System	21 Nov 2020 00:22:36

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:51:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history of GLAUCOMA worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 May 2021 10:15:16
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history of GLAUCOMA worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' answered with 'No indication that glaucoma worsened. Medication was changed while subject was hospitalized. ' (Site from DM).	Lyly Dang (b) (4)	28 Apr 2021 18:57:37
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history of GLAUCOMA worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 09:50:11
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)	08 Mar 2021 23:19:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Mar 2021 23:19:55
Data point term sent to Coder	System	08 Mar 2021 20:36:13

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:51:21

[Name of Medication](#)

Audit	User	Time (GMT)
Coding entries removed.	lauren clement (b) (4)	08 Mar 2021 20:35:58
Coding entries removed.	lauren clement (b) (4)	08 Mar 2021 20:35:58
User entered 'ALPHAGAN 0.2%' reason for change: Data Entry Error	lauren clement (b) (4)	08 Mar 2021 20:35:58
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)	15 Dec 2020 19:53:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Dec 2020 19:53:00
Data point term sent to Coder	System	15 Dec 2020 19:51:47
User entered 'ALPHAGAN'	Heather Cherniawski (b) (4)	15 Dec 2020 19:51:04

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:51:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered 'No (N)'	Heather Cherniawski	15 Dec 2020 19:51:04
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:51:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 14:29:09
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening should be recorded, and update con med indication or provide clarification. ' answered with 'Providing physician reported stable in MR, but did have change in meds, did not note why he changed her meds. Keep as is, not a worsening of condition.' (Site from DM).	lauren clement (b) (4)	08 Mar 2021 20:35:29
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 03:38:08
User entered 'GLAUCOMA'	Heather Cherniawski (b) (4)	15 Dec 2020 19:51:04

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:51:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User closed query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 14:36:32
Query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate.' answered with 'ok' (Site from DM).	lauren clement (b) (4)	08 Mar 2021 20:36:05
User entered '1' reason for change: Data Entry Error	lauren clement (b) (4)	08 Mar 2021 20:35:58
User opened query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 03:38:24
User entered '0.2'	Heather Cherniawski (b) (4)	15 Dec 2020 19:51:04

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:51:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered 'Other (OTHER)'	Heather Cherniawski	15 Dec 2020 19:51:04
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:51:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered 'drop' reason for change: Data Entry Error	lauren clement (b) (4)	08 Mar 2021 20:35:58
User entered '%'	Heather Cherniawski	15 Dec 2020 19:51:04
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:51:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered 'twice daily (BID)'	Heather Cherniawski	15 Dec 2020 19:51:04
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:51:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered empty.	Heather Cherniawski	15 Dec 2020 19:51:04
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:51:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 14:36:35
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'ok' (Site from DM).	lauren clement (b) (4)	08 Mar 2021 20:36:10
User entered 'Other (OTHER)' reason for change: Data Entry Error	lauren clement (b) (4)	08 Mar 2021 20:35:58
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 03:38:35
User entered 'Intraocular (INTRAOCULAR)'	Heather Cherniawski (b) (4)	15 Dec 2020 19:51:04

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:51:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered 'ophthalmic' reason for change: Data Entry Error	lauren clement (b) (4)	08 Mar 2021 20:35:58
User entered empty.	Heather Cherniawski	15 Dec 2020 19:51:04
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered '30 Nov 2020'	Heather Cherniawski	15 Dec 2020 19:51:04
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered '0'	Heather Cherniawski	15 Dec 2020 19:51:04
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:51:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered 'Yes (Y)'	Heather Cherniawski	15 Dec 2020 19:51:04
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:51:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered empty.	Heather Cherniawski	15 Dec 2020 19:51:04
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:51:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered 'No (N)'	Heather Cherniawski	15 Dec 2020 19:51:04
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:51:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '2'	System	15 Dec 2020 19:51:04

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:51:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '1'	System	15 Dec 2020 19:51:04

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:51:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '804 (804)'	System	15 Dec 2020 19:51:04

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:51:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: INDOLE DERIVATIVES, PRODUCT: LURASIDONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 00:30:56
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 00:30:56
	(b) (4)	
Data point term sent to Coder	System	15 Dec 2020 19:53:48
User entered 'LARASIDONE'	Heather Cherniawski	15 Dec 2020 19:53:12
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:51:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:02
User entered 'No (N)'	Heather Cherniawski	15 Dec 2020 19:53:12
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:51:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:02
User entered 'SEVERE EPISODE OF RECURRENT MAJOR DEPPRESSIVE DISORDER'	Heather Cherniawski (b) (4)	15 Dec 2020 19:53:12

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:51:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:02
User entered '40'	Heather Cherniawski	15 Dec 2020 19:53:12
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:51:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:02
User entered 'mg (mg)'	Heather Cherniawski	15 Dec 2020 19:53:12
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:51:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:02
User entered empty.	Heather Cherniawski	15 Dec 2020 19:53:12
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:51:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:02
User entered 'once daily (QD)'	Heather Cherniawski	15 Dec 2020 19:53:12
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:51:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:02
User entered empty.	Heather Cherniawski	15 Dec 2020 19:53:12
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:51:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:02
User entered 'Oral (ORAL)'	Heather Cherniawski	15 Dec 2020 19:53:12
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:51:21

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:02
User entered empty.	Heather Cherniawski	15 Dec 2020 19:53:12
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:02
User entered '30 Nov 2020'	Heather Cherniawski	15 Dec 2020 19:53:12
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:02
User entered '0'	Heather Cherniawski	15 Dec 2020 19:53:12
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:51:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User closed query 'Per DM RQ: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:10:33
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
Query 'Per DM RQ: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'Unknown if medication stopped as subject was withdrawn from the study ' (Site from DM). DataPoint Un-verified.	Lyly Dang (b) (4)	28 Apr 2021 18:49:06
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:08
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	27 Apr 2021 15:16:02
User opened query 'Per DM RQ: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 13:32:18
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'Although AE was resolved due to finding stability, subject will be on this drug as ongoing to produce stability. Keep as is' (Site from DM).	lauren clement (b) (4)	08 Mar 2021 20:42:32
PRODUCTION RELEASE (v12.003 EAB) (1725)		2908 of 3250

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:51:21

[Ongoing?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Feb 2021 07:06:19
	Heather Cherniawski (b) (4)	15 Dec 2020 19:53:12

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:51:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 22:37:22
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Un-verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:14
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:02
User entered empty.	Heather Cherniawski	15 Dec 2020 19:53:12
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:51:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:02
User entered 'No (N)'	Heather Cherniawski	15 Dec 2020 19:53:12
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:51:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '1'	System	15 Dec 2020 19:53:12

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:51:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '1'	System	15 Dec 2020 19:53:12

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:51:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '804 (804)'	System	15 Dec 2020 19:53:12

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:51:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:44
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)	17 Dec 2020 17:54:53
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 17:54:53
	(b) (4)	
Data point term sent to Coder	System	15 Dec 2020 19:54:49
User entered 'CLONAZEPAM'	Heather Cherniawski	15 Dec 2020 19:54:23
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:51:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:44
User entered 'No (N)'	Heather Cherniawski	15 Dec 2020 19:54:23
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:51:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:44
User entered 'SEVERE EPISODE OF RECURRENT MAJOR DEPPRESSIVE DISORDER'	Heather Cherniawski (b) (4)	15 Dec 2020 19:54:23

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:51:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:44
User entered '0.5'	Heather Cherniawski	15 Dec 2020 19:54:23
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:51:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:44
User entered 'mg (mg)'	Heather Cherniawski	15 Dec 2020 19:54:23
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:51:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:44
User entered empty.	Heather Cherniawski	15 Dec 2020 19:54:23
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:51:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:44
User entered 'twice daily (BID)'	Heather Cherniawski	15 Dec 2020 19:54:23
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:51:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:44
User entered empty.	Heather Cherniawski	15 Dec 2020 19:54:23
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:51:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:44
User entered 'Oral (ORAL)'	Heather Cherniawski	15 Dec 2020 19:54:23
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:51:21

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:44
User entered empty.	Heather Cherniawski	15 Dec 2020 19:54:23
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:44
User entered '30 Nov 2020'	Heather Cherniawski	15 Dec 2020 19:54:23
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:44
User entered '0'	Heather Cherniawski	15 Dec 2020 19:54:23
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:51:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:44
User entered 'Yes (Y)'	Heather Cherniawski	15 Dec 2020 19:54:23
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:51:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:44
User entered empty.	Heather Cherniawski	15 Dec 2020 19:54:23
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:51:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:44
User entered 'No (N)'	Heather Cherniawski	15 Dec 2020 19:54:23
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:51:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '2'	System	15 Dec 2020 19:54:23

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:51:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '1'	System	15 Dec 2020 19:54:23

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:51:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '804 (804)'	System	15 Dec 2020 19:54:23

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:51:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 01:22:48
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 01:22:48
	(b) (4)	
Data point term sent to Coder	System	15 Dec 2020 19:56:49
User entered 'LORAZEPAM'	Heather Cherniawski	15 Dec 2020 19:56:25
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:51:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:47
User entered 'No (N)'	Heather Cherniawski	15 Dec 2020 19:56:25
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:51:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:47
User entered 'SEVERE EPISODE OF RECURRENT MAJOR DEPPRESSIVE DISORDER'	Heather Cherniawski (b) (4)	15 Dec 2020 19:56:25

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:51:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:47
User entered '1'	Heather Cherniawski	15 Dec 2020 19:56:25
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:51:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:47
User entered 'mg (mg)'	Heather Cherniawski	15 Dec 2020 19:56:25
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:51:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:47
User entered empty.	Heather Cherniawski	15 Dec 2020 19:56:25
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:51:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:47
User entered 'as needed (PRN)'	Heather Cherniawski	15 Dec 2020 19:56:25
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:51:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:47
User entered empty.	Heather Cherniawski	15 Dec 2020 19:56:25
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:51:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:47
User entered 'Oral (ORAL)'	Heather Cherniawski	15 Dec 2020 19:56:25
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:51:21

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:47
User entered empty.	Heather Cherniawski	15 Dec 2020 19:56:25
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:47
User entered '18 Nov 2020'	Heather Cherniawski	15 Dec 2020 19:56:25
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:47
User entered '0'	Heather Cherniawski	15 Dec 2020 19:56:25
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:51:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:47
User entered 'No (N)'	Heather Cherniawski	15 Dec 2020 19:56:25
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:51:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:47
User entered '18 Nov 2020'	Heather Cherniawski	15 Dec 2020 19:56:25
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:51:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:47
User entered 'No (N)'	Heather Cherniawski	15 Dec 2020 19:56:25
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:51:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered empty.	System	15 Dec 2020 19:56:25

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:51:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered empty.	System	15 Dec 2020 19:56:25

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:51:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered empty.	System	15 Dec 2020 19:56:25

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:51:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: OLANZAPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 10:05:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 10:05:39
Data point term sent to Coder	System	15 Dec 2020 19:58:50
User entered 'OLANZAPINE'	Heather Cherniawski (b) (4)	15 Dec 2020 19:57:52

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:51:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:50
User entered 'No (N)'	Heather Cherniawski	15 Dec 2020 19:57:52
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:51:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:50
User entered 'SEVERE EPISODE OF RECURRENT MAJOR DEPPRESSIVE DISORDER'	Heather Cherniawski (b) (4)	15 Dec 2020 19:57:52

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:51:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:50
User entered '10'	Heather Cherniawski	15 Dec 2020 19:57:52
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:51:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:50
User entered 'mg (mg)'	Heather Cherniawski	15 Dec 2020 19:57:52
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:51:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:50
User entered empty.	Heather Cherniawski	15 Dec 2020 19:57:52
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:51:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:50
User entered 'as needed (PRN)'	Heather Cherniawski	15 Dec 2020 19:57:52
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:51:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:50
User entered empty.	Heather Cherniawski	15 Dec 2020 19:57:52
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:51:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:50
User entered 'Oral (ORAL)'	Heather Cherniawski	15 Dec 2020 19:57:52
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:51:21

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:50
User entered empty.	Heather Cherniawski	15 Dec 2020 19:57:52
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:50
User entered '18 Nov 2020'	Heather Cherniawski	15 Dec 2020 19:57:52
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:50
User entered '0'	Heather Cherniawski	15 Dec 2020 19:57:52
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:51:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:50
User entered 'No (N)'	Heather Cherniawski	15 Dec 2020 19:57:52
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:51:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:50
User entered '18 Nov 2020'	Heather Cherniawski	15 Dec 2020 19:57:52
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:51:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:50
User entered 'No (N)'	Heather Cherniawski	15 Dec 2020 19:57:52
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:51:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered empty.	System	15 Dec 2020 19:57:52

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:51:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered empty.	System	15 Dec 2020 19:57:52

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:51:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered empty.	System	15 Dec 2020 19:57:52

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:51:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:53
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)	16 Dec 2020 00:17:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 00:17:40
Data point term sent to Coder	System	15 Dec 2020 19:59:50
User entered 'QUETIAPINE'	Heather Cherniawski (b) (4)	15 Dec 2020 19:58:58

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:51:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:53
User entered 'No (N)'	Heather Cherniawski	15 Dec 2020 19:58:58
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:51:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:53
User entered 'SEVERE EPISODE OF RECURRENT MAJOR DEPPRESSIVE DISORDER'	Heather Cherniawski (b) (4)	15 Dec 2020 19:58:58

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:51:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:53
User entered '400'	Heather Cherniawski	15 Dec 2020 19:58:58
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:51:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:53
User entered 'mg (mg)'	Heather Cherniawski	15 Dec 2020 19:58:58
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:51:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:53
User entered empty.	Heather Cherniawski	15 Dec 2020 19:58:58
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:51:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:53
User entered 'as needed (PRN)'	Heather Cherniawski	15 Dec 2020 19:58:58
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:51:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:53
User entered empty.	Heather Cherniawski	15 Dec 2020 19:58:58
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:51:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:53
User entered 'Oral (ORAL)'	Heather Cherniawski	15 Dec 2020 19:58:58
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:51:21

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:53
User entered empty.	Heather Cherniawski	15 Dec 2020 19:58:58
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:53
User entered '18 Nov 2020'	Heather Cherniawski	15 Dec 2020 19:58:58
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:53
User entered '0'	Heather Cherniawski	15 Dec 2020 19:58:58
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:51:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:53
User entered 'No (N)'	Heather Cherniawski	15 Dec 2020 19:58:58
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:51:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:53
User entered '18 Nov 2020'	Heather Cherniawski	15 Dec 2020 19:58:58
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:51:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:53
User entered 'No (N)'	Heather Cherniawski	15 Dec 2020 19:58:58
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:51:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered empty.	System	15 Dec 2020 19:58:58

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:51:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered empty.	System	15 Dec 2020 19:58:58

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:51:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered empty.	System	15 Dec 2020 19:58:58

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:51:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:56
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)	15 Dec 2020 21:03:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Dec 2020 21:03:57
Data point term sent to Coder	System	15 Dec 2020 20:00:53
User entered 'TRAZODONE'	Heather Cherniawski (b) (4)	15 Dec 2020 20:00:07

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:51:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:56
User entered 'No (N)'	Heather Cherniawski	15 Dec 2020 20:00:07
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:51:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:56
User entered 'SEVERE EPISODE OF RECURRENT MAJOR DEPPRESSIVE DISORDER'	Heather Cherniawski (b) (4)	15 Dec 2020 20:00:07

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:51:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:56
User entered '100'	Heather Cherniawski	15 Dec 2020 20:00:07
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:51:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:56
User entered 'mg (mg)'	Heather Cherniawski	15 Dec 2020 20:00:07
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:51:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:56
User entered empty.	Heather Cherniawski	15 Dec 2020 20:00:07
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:51:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:56
User entered 'as needed (PRN)'	Heather Cherniawski	15 Dec 2020 20:00:07
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:51:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:56
User entered empty.	Heather Cherniawski	15 Dec 2020 20:00:07
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:51:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:56
User entered 'Oral (ORAL)'	Heather Cherniawski	15 Dec 2020 20:00:07
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:51:21

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:56
User entered empty.	Heather Cherniawski	15 Dec 2020 20:00:07
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:51:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:56
User entered '19 Nov 2020'	Heather Cherniawski	15 Dec 2020 20:00:07
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:56
User entered '0'	Heather Cherniawski	15 Dec 2020 20:00:07
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:51:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:56
User entered 'No (N)'	Heather Cherniawski	15 Dec 2020 20:00:07
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:51:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:56
User entered '19 Nov 2020'	Heather Cherniawski	15 Dec 2020 20:00:07
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:51:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:16:56
User entered 'No (N)'	Heather Cherniawski	15 Dec 2020 20:00:07
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:51:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered empty.	System	15 Dec 2020 20:00:07

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:51:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered empty.	System	15 Dec 2020 20:00:07

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:51:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered empty.	System	15 Dec 2020 20:00:07

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:51:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:17:01
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: HYDROXYZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 21:51:50
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 21:51:50
	(b) (4)	
Data point term sent to Coder	System	15 Dec 2020 20:02:56
User entered 'HYDROXYZINE'	Heather Cherniawski	15 Dec 2020 20:02:12
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:51:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:17:01
User entered 'No (N)'	Heather Cherniawski	15 Dec 2020 20:02:12
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:51:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:17:01
User entered 'SEVERE EPISODE OF RECURRENT MAJOR DEPPRESSIVE DISORDER'	Heather Cherniawski (b) (4)	15 Dec 2020 20:02:12

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:51:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:17:01
User entered '50'	Heather Cherniawski	15 Dec 2020 20:02:12
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:51:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:17:01
User entered 'mg (mg)'	Heather Cherniawski	15 Dec 2020 20:02:12
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:51:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:17:01
User entered empty.	Heather Cherniawski	15 Dec 2020 20:02:12
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:51:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:17:01
User entered 'as needed (PRN)'	Heather Cherniawski	15 Dec 2020 20:02:12
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:51:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:17:01
User entered empty.	Heather Cherniawski	15 Dec 2020 20:02:12
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:51:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:17:01
User entered 'Oral (ORAL)'	Heather Cherniawski	15 Dec 2020 20:02:12
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:51:21

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:17:01
User entered empty.	Heather Cherniawski	15 Dec 2020 20:02:12
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:17:01
User entered '19 Nov 2020'	Heather Cherniawski	15 Dec 2020 20:02:12
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:17:01
User entered '0'	Heather Cherniawski	15 Dec 2020 20:02:12
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:51:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:17:01
User entered 'No (N)'	Heather Cherniawski	15 Dec 2020 20:02:12
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:51:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:17:01
User entered '19 Nov 2020'	Heather Cherniawski	15 Dec 2020 20:02:12
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:51:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:17:01
User entered 'No (N)'	Heather Cherniawski	15 Dec 2020 20:02:12
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:51:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered empty.	System	15 Dec 2020 20:02:12

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:51:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered empty.	System	15 Dec 2020 20:02:12

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:51:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered empty.	System	15 Dec 2020 20:02:12

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:51:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
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)	29 Apr 2021 23:04:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Apr 2021 23:04:08
Data point term sent to Coder	System	29 Apr 2021 17:03:21
Coding entries removed.	Breanna Galibert (b) (4)	29 Apr 2021 17:02:48
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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)	17 Dec 2020 18:07:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 18:07:43
Data point term sent to Coder	System	16 Dec 2020 17:26:53
Data point term sent to Coder	System	15 Dec 2020 20:19:08
User entered 'COSOPT (22.3-6.8MG/ML)'	Heather Cherniawski (b) (4)	15 Dec 2020 20:18:47

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:51:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered 'No (N)'	Heather Cherniawski	15 Dec 2020 20:18:47
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:51:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered 'Glaucoma' reason for change: Data Entry Error	Lyly Dang (b) (4)	16 Dec 2020 17:26:50
User entered 'SEVERE EPISODE OF RECURRENT MAJOR DEPPRESSIVE DISORDER'	Heather Cherniawski (b) (4)	15 Dec 2020 20:18:47

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:51:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered '1'	Heather Cherniawski	15 Dec 2020 20:18:47
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:51:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered 'Other (OTHER)'	Heather Cherniawski	15 Dec 2020 20:18:47
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:51:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered 'DROP (22.3-6.8MG/ML)'	Heather Cherniawski	15 Dec 2020 20:18:47
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:51:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered 'as needed (PRN)'	Heather Cherniawski	15 Dec 2020 20:18:47
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:51:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered empty.	Heather Cherniawski	15 Dec 2020 20:18:47
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:51:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
Signature has been broken.	Breanna Galibert (b) (4)	29 Apr 2021 17:02:48
	(b) (4)	
User entered 'Other (OTHER)' reason for change: Data Entry Error	Breanna Galibert (b) (4)	29 Apr 2021 17:02:48
	(b) (4)	
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered 'Intraocular (INTRAOCULAR)'	Heather Cherniawski	15 Dec 2020 20:18:47
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:51:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
Signature has been broken.	Breanna Galibert (b) (4)	29 Apr 2021 17:02:48
	(b) (4)	
User entered 'ophthalmic' reason for change: Data Entry Error	Breanna Galibert (b) (4)	29 Apr 2021 17:02:48
	(b) (4)	
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered empty.	Heather Cherniawski	15 Dec 2020 20:18:47
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered '18 Nov 2020'	Heather Cherniawski	15 Dec 2020 20:18:47
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered '0'	Heather Cherniawski	15 Dec 2020 20:18:47
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:51:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered 'No (N)'	Heather Cherniawski	15 Dec 2020 20:18:47
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:51:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered '18 Nov 2020'	Heather Cherniawski	15 Dec 2020 20:18:47
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:51:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered 'No (N)'	Heather Cherniawski	15 Dec 2020 20:18:47
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:51:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered empty.	System	15 Dec 2020 20:18:47

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:51:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered empty.	System	15 Dec 2020 20:18:47

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:51:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered empty.	System	15 Dec 2020 20:18:47

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:51:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
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)	08 Mar 2021 23:19:55
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Mar 2021 23:19:55
	(b) (4)	
Data point term sent to Coder	System	08 Mar 2021 20:38:15
Coding entries removed.	lauren clement (b) (4)	08 Mar 2021 20:37:25
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)	15 Dec 2020 21:46:59
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Dec 2020 21:46:59
	(b) (4)	
Data point term sent to Coder	System	15 Dec 2020 20:24:16
User entered 'ALPHAGAN (0.2%)'	Heather Cherniawski	15 Dec 2020 20:23:32
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:51:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered 'No (N)'	Heather Cherniawski	15 Dec 2020 20:23:32
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:51:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered 'GLAUCOMA'	Heather Cherniawski	15 Dec 2020 20:23:32
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:51:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered '1'	Heather Cherniawski	15 Dec 2020 20:23:32
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:51:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered 'Other (OTHER)'	Heather Cherniawski	15 Dec 2020 20:23:32
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:51:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered 'DROP' reason for change: Data Entry Error	lauren clement (b) (4)	08 Mar 2021 20:37:25
User entered 'DROP (0.2%)'	Heather Cherniawski	15 Dec 2020 20:23:32
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:51:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered 'twice daily (BID)'	Heather Cherniawski	15 Dec 2020 20:23:32
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:51:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered empty.	Heather Cherniawski	15 Dec 2020 20:23:32
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:51:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 17:23:28
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'ok' (Site from DM).	lauren clement (b) (4)	08 Mar 2021 20:37:31
User entered 'Other (OTHER)' reason for change: Data Entry Error	lauren clement (b) (4)	08 Mar 2021 20:37:25
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 07:05:43
User entered 'Intraocular (INTRAOCULAR)'	Heather Cherniawski (b) (4)	15 Dec 2020 20:23:32

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:51:21

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered 'ophthalmic' reason for change: Data Entry Error	lauren clement (b) (4)	08 Mar 2021 20:37:25
User entered empty.	Heather Cherniawski	15 Dec 2020 20:23:32
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered '19 Nov 2020'	Heather Cherniawski	15 Dec 2020 20:23:32
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:51:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered '0'	Heather Cherniawski	15 Dec 2020 20:23:32
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:51:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered 'No (N)'	Heather Cherniawski	15 Dec 2020 20:23:32
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:51:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered '19 Nov 2020'	Heather Cherniawski	15 Dec 2020 20:23:32
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:51:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered 'No (N)'	Heather Cherniawski	15 Dec 2020 20:23:32
	(b) (4)	

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:51:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '2'	System	15 Dec 2020 20:23:32

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:51:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '1'	System	15 Dec 2020 20:23:32

US3812059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:51:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '804 (804)'	System	15 Dec 2020 20:23:32

US3812059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:51:21

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 22:29:28
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered 'Yes (Y)'	Karen Knapp (b) (4)	03 Sep 2020 12:36:25
	(b) (4)	

US3812059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:51:21

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:05:47
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 22:29:46
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered '26 Oct 2020'	lauren clement (b) (4)	08 Mar 2021 20:20:03

US3812059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:51:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:05:47
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 22:29:46
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered 'URINE DRUG SCREEN'	lauren clement (b) (4)	08 Mar 2021 20:20:03

US3812059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:51:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:05:47
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 22:29:46
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered 'Adverse Event (AE)'	lauren clement (b) (4)	08 Mar 2021 20:20:03

US3812059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:51:21

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:05:47
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 22:29:46
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered empty.	lauren clement (b) (4)	08 Mar 2021 20:20:03

US3812059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:51:21

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 22:29:46
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
Query 'Data entered is non-conformant. Please correct.' canceled (Site from System).	KC Joubran (b) (4)	23 Apr 2021 13:50:10
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Mar 2021 20:22:55
User entered 'UN Nov 2020' (non-conformant).	lauren clement (b) (4)	08 Mar 2021 20:22:55

US3812059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:51:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 22:29:46
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered 'SUBSTANCE ABUSE TREATMENT PROGRAM' reason for change: Data Entry Error	Angie Kean (b) (4)	25 Mar 2021 20:24:45
	(b) (4)	
User entered 'SUBSTANCE USE TREATMENT PROGRAM'	lauren clement (b) (4)	08 Mar 2021 20:22:55

US3812059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:51:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User closed query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	01 May 2021 12:36:08
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 22:29:46
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
Query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' answered with 'ok' (Site from DM).	Lyly Dang (b) (4)	28 Apr 2021 18:50:47
User opened query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 22:32:39
User entered 'Adverse Event (AE)'	lauren clement (b) (4)	08 Mar 2021 20:22:55

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:51:21

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 22:29:46
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:54
User entered empty.	lauren clement (b) (4)	08 Mar 2021 20:22:55

US3812059

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:51:21

Date of study discontinuation/completion (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:34:38
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:31
User entered '23 Mar 2021' reason for change: Data Entry Error	Lyly Dang (b) (4)	23 Mar 2021 21:10:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	19 Mar 2021 12:34:02
Query 'Data is required. Please complete.' answered with 'subject being followed for safety' (Site from System).	Lyly Dang (b) (4)	15 Mar 2021 14:12:13
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 14:11:49
Signature has been broken.	Lyly Dang (b) (4)	15 Mar 2021 14:11:49
User entered empty; reason for change Data Entry Error	Lyly Dang (b) (4)	15 Mar 2021 14:11:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered '29 Jan 2021'	Lyly Dang (b) (4)	01 Feb 2021 12:43:16

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:51:21

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:34:38
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:31
User entered 'Other (OTHER)' reason for change: Data Entry Error	Lyly Dang (b) (4)	23 Mar 2021 21:10:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	19 Mar 2021 12:34:04
Query 'Data is required. Please complete.' answered with 'subject being followed for safety' (Site from System).	Lyly Dang (b) (4)	15 Mar 2021 14:12:15
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 14:11:49
Signature has been broken.	Lyly Dang (b) (4)	15 Mar 2021 14:11:49
User entered empty; reason for change Data Entry Error	Lyly Dang (b) (4)	15 Mar 2021 14:11:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered 'Lost To Follow-up (LOST TO FOLLOW-UP)'	Lyly Dang (b) (4)	01 Feb 2021 12:43:16

US3812059

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:51:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:34:38
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:31
Signature has been broken.	Lyly Dang (b) (4)	23 Mar 2021 21:10:51
User entered 'subject would like to receive the COVID-19 vaccine outside of the study' reason for change: Data Entry Error	Lyly Dang (b) (4)	23 Mar 2021 21:10:51
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered empty.	Lyly Dang (b) (4)	01 Feb 2021 12:43:16

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:51:21

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:34:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered empty.	Lyly Dang (b) (4)	01 Feb 2021 12:43:16

US3812059

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:51:21

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:34:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered empty.	Lyly Dang (b) (4)	01 Feb 2021 12:43:16

US3812059

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:51:21

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:34:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered empty.	Lyly Dang (b) (4)	01 Feb 2021 12:43:16

US3812059

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:51:21

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:34:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered empty.	Lyly Dang (b) (4)	01 Feb 2021 12:43:16

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[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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

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

Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:33
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered 'lauren'	System	29 Apr 2021 15:02:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:33
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered 'clement'	System	29 Apr 2021 15:02:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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

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Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:21

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:33
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered empty.	System	29 Apr 2021 15:02:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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

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Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:21

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:33
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered empty.	System	29 Apr 2021 15:02:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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

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Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:21

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:33
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered 'MO'	System	29 Apr 2021 15:02:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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'	Any Penly (b) (4)	12 Nov 2020 15:41:50
	(b) (4)	

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Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:21

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:33
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered empty.	System	29 Apr 2021 15:02:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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

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Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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

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Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

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[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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

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Folder: SAE USA-US111-2020-MRNA-1273-P301000006

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Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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

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Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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

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Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:21

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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

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Folder: SAE USA-US111-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:21

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:33
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered 'lauren'	System	29 Apr 2021 15:02:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:33
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered 'clement'	System	29 Apr 2021 15:02:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:33
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered empty.	System	29 Apr 2021 15:02:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:33
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered empty.	System	29 Apr 2021 15:02:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:33
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered 'MO'	System	29 Apr 2021 15:02:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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'	Any 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: 10 Jun 2021 09:51:21

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:33
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered empty.	System	29 Apr 2021 15:02:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:33
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered 'lauren'	System	29 Apr 2021 15:02:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:33
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered 'clement'	System	29 Apr 2021 15:02:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:33
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered empty.	System	29 Apr 2021 15:02:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:33
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered empty.	System	29 Apr 2021 15:02:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:33
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered 'MO'	System	29 Apr 2021 15:02:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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'	Any 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: 10 Jun 2021 09:51:21

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:33
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered empty.	System	29 Apr 2021 15:02:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:33
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered 'lauren'	System	29 Apr 2021 15:02:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:33
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered 'clement'	System	29 Apr 2021 15:02:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:33
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered empty.	System	29 Apr 2021 15:02:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:33
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered empty.	System	29 Apr 2021 15:02:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:33
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered 'MO'	System	29 Apr 2021 15:02:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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'	Any 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: 10 Jun 2021 09:51:21

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:33
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered empty.	System	29 Apr 2021 15:02:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
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: 10 Jun 2021 09:51:21

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
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: 10 Jun 2021 09:51:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
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: 10 Jun 2021 09:51:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
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: 10 Jun 2021 09:51:21

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
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

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[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:03:49
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered 'lauren'	System	29 Apr 2021 15:02:58
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 15:16:24
User entered 'Larkin'	System	21 Nov 2020 15:15:12

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Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:03:49
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered 'clement'	System	29 Apr 2021 15:02:58
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:03:49
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered empty.	System	29 Apr 2021 15:02:58
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:03:49
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered empty.	System	29 Apr 2021 15:02:58
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:03:49
User entered 'MO'	System	29 Apr 2021 15:02:58

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:21

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:03:49
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered empty.	System	29 Apr 2021 15:02:58
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:39:57
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: 10 Jun 2021 09:51:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '5'	System	29 Apr 2021 15:02:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '4'	System	17 Dec 2020 15:05:54
User entered '3'	System	16 Dec 2020 14:18:18
User entered '2'	System	02 Dec 2020 16:40:38
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: 10 Jun 2021 09:51:21

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
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: 10 Jun 2021 09:51:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
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: 10 Jun 2021 09:51:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
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: 10 Jun 2021 09:51:21

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
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: 10 Jun 2021 09:51:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:03:49
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered 'lauren'	System	29 Apr 2021 15:02:58
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:03:49
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered 'clement'	System	29 Apr 2021 15:02:58
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:03:49
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered empty.	System	29 Apr 2021 15:02:58
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:03:49
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered empty.	System	29 Apr 2021 15:02:58
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:03:49
User entered 'MO'	System	29 Apr 2021 15:02:58

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:21

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:03:49
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered empty.	System	29 Apr 2021 15:02:58
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:39:57
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: 10 Jun 2021 09:51:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '5'	System	29 Apr 2021 15:02:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '4'	System	17 Dec 2020 15:05:54
User entered '3'	System	16 Dec 2020 14:18:18
User entered '2'	System	02 Dec 2020 16:40:38
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: 10 Jun 2021 09:51:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
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: 10 Jun 2021 09:51:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:39:57
User entered '1'	(b) (4), (b) (6)	21 Nov 2020 15:16:37

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:21

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
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: 10 Jun 2021 09:51:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
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: 10 Jun 2021 09:51:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
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: 10 Jun 2021 09:51:21

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
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: 10 Jun 2021 09:51:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:03:49
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered 'lauren'	System	29 Apr 2021 15:02:58
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:03:49
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered 'clement'	System	29 Apr 2021 15:02:58
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:03:49
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered empty.	System	29 Apr 2021 15:02:58
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:03:49
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered empty.	System	29 Apr 2021 15:02:58
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:03:49
User entered 'MO'	System	29 Apr 2021 15:02:58

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:21

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:03:49
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered empty.	System	29 Apr 2021 15:02:58
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:39:57
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: 10 Jun 2021 09:51:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '5'	System	29 Apr 2021 15:02:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '4'	System	17 Dec 2020 15:05:54
User entered '3'	System	16 Dec 2020 14:18:18
User entered '2'	System	02 Dec 2020 16:40:38
User entered '1'	System	21 Nov 2020 15:16:37

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:51:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '02/Dec/2020 16:40'	System	02 Dec 2020 16:40:38

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:51:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 14:18:02
User entered '1'	(b) (4), (b) (6)	02 Dec 2020 16:40:38

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:21

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
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: 10 Jun 2021 09:51:21

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
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: 10 Jun 2021 09:51:21

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
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: 10 Jun 2021 09:51:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
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: 10 Jun 2021 09:51:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
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: 10 Jun 2021 09:51:21

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
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: 10 Jun 2021 09:51:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:03:49
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered 'lauren'	System	29 Apr 2021 15:02:58
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:03:49
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered 'clement'	System	29 Apr 2021 15:02:58
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:03:49
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered empty.	System	29 Apr 2021 15:02:58
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:03:49
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered empty.	System	29 Apr 2021 15:02:58
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:03:49
User entered 'MO'	System	29 Apr 2021 15:02:58

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:21

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:03:49
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered empty.	System	29 Apr 2021 15:02:58
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:39:57
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: 10 Jun 2021 09:51:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '5'	System	29 Apr 2021 15:02:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '4'	System	17 Dec 2020 15:05:54
User entered '3'	System	16 Dec 2020 14:18:18
User entered '2'	System	02 Dec 2020 16:40:38
User entered '1'	System	21 Nov 2020 15:16:37

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:51:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered '16/Dec/2020 14:18'	System	16 Dec 2020 14:18:18

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:51:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:03:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '1'	(b) (4), (b) (6)	16 Dec 2020 14:18:18

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:21

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
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: 10 Jun 2021 09:51:21

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
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: 10 Jun 2021 09:51:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
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: 10 Jun 2021 09:51:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
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: 10 Jun 2021 09:51:21

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
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: 10 Jun 2021 09:51:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:03:49
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered 'lauren'	System	29 Apr 2021 15:02:58
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:03:49
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered 'clement'	System	29 Apr 2021 15:02:58
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:03:49
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered empty.	System	29 Apr 2021 15:02:58
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:03:49
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered empty.	System	29 Apr 2021 15:02:58
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:03:49
User entered 'MO'	System	29 Apr 2021 15:02:58

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:21

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:03:49
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered empty.	System	29 Apr 2021 15:02:58
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:39:57
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: 10 Jun 2021 09:51:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '5'	System	29 Apr 2021 15:02:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '4'	System	17 Dec 2020 15:05:54
User entered '3'	System	16 Dec 2020 14:18:18
User entered '2'	System	02 Dec 2020 16:40:38
User entered '1'	System	21 Nov 2020 15:16:37

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:51:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
User entered '17/Dec/2020 10:05'	System	17 Dec 2020 15:05:54

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:51:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 15:06:01
User entered '1'	(b) (4), (b) (6)	17 Dec 2020 15:05:54

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:21

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
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: 10 Jun 2021 09:51:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
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: 10 Jun 2021 09:51:21

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
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: 10 Jun 2021 09:51:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:03:49
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered 'lauren'	System	29 Apr 2021 15:02:58
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:03:49
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered 'clement'	System	29 Apr 2021 15:02:58
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:03:49
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered empty.	System	29 Apr 2021 15:02:58
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:03:49
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered empty.	System	29 Apr 2021 15:02:58
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:03:49
User entered 'MO'	System	29 Apr 2021 15:02:58

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:21

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:03:49
Un-reviewed for Safety.	System	29 Apr 2021 15:02:58
DataPoint Un-verified.	System	29 Apr 2021 15:02:58
Signature has been broken.	System	29 Apr 2021 15:02:58
User entered empty.	System	29 Apr 2021 15:02:58
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
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: 10 Jun 2021 09:51:21

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:50:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:39:57
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: 10 Jun 2021 09:51:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User entered '5'	System	29 Apr 2021 15:02:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:34:52
	(b) (4)	
User entered '4'	System	17 Dec 2020 15:05:54
User entered '3'	System	16 Dec 2020 14:18:18
User entered '2'	System	02 Dec 2020 16:40:38
User entered '1'	System	21 Nov 2020 15:16:37

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:51:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:41
User entered '29/Apr/2021 10:59'	System	29 Apr 2021 15:02:58

US3812059

Folder: SAE USA-US111-2020-MRNA-1273-P301000013

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:51:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:55
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:29
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:42:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 15:03:49
User entered '1'	(b) (4), (b) (6)	29 Apr 2021 15:02:58