

US3202057 (Prod: WR-ClinSearch, LLC)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:05:41

All time stamps listed in this document are displayed in GMT

US3202057

Form: Participant Creation

Data signed: (b) (4) 09 Apr 2021 13:28:04

Generated On: 11 Aug 2021 22:05:41

[Participant ID](#)

US3202057

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

US3202057

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Date of Birth (MMM yyyy)	(b) (6) 1990
Age	30
Age Units	YEARS
Age (Derived)	30
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

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

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

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

Was participant enrolled in the study? Yes
No

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

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

US3202057

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Condition	LYRICA CAUSES HIVES
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

US3202057

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	07 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:17 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 14:17
Height (<i>xxx.x</i>)	164.0 cm
Weight (<i>xxx.x</i>)	67.1 kg
BMI (<i>xxx.x</i>)	24.94795 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

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: Screening

Form: Childbearing Potential

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Date of assessment (*dd MMM yyyy*) 07 AUG 2020

Is the participant of childbearing potential? Yes
No

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	07 AUG 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	07 AUG 2020
Collection time	14:00
Collection date and time (derived)	07 AUG 2020 14:00

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 01:52:15

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes No

Specify _____

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 01:52:15

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 07 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) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

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

What was the participant's randomization number? 101985

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) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

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) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	07 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:17 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 14:17
Temperature (<i>xxx.x</i>)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	83 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	66 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	07 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	16:35 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 16:35
Temperature (<i>xxx.x</i>)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	91 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	69 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

07 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

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) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Was study treatment given? Yes No

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 16:04 (24 HR)

Treatment Date and Time (derived) 7 AUG 2020 16:04

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) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	07 AUG 2020
Collection time (<i>00:00-23:59</i>)	14:34 (24 HR)
Collection date and time (derived)	07 AUG 2020 14:34

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Collection date (<i>dd MMM yyyy</i>)			07 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:32	07 AUG 2020 14:32
Nasopharyngeal Swab 2	No		

US3202057

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.1 °F

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

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

PC Time Stamp 07 AUG 2020 16:38

PC Open Date & Time 07 AUG 2020 16:24

PC Close Date & Time 07 AUG 2020 18:54

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.3 °F

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

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

PC Time Stamp	07 AUG 2020 22:37
PC Open Date & Time	07 AUG 2020 19:49
PC Close Date & Time	08 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:05:41

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	09 AUG 2020 00:32
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:05:41

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.7 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	09 AUG 2020 22:20
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:05:41

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	10 AUG 2020 13:35
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.1 °F

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

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

PC Time Stamp	11 AUG 2020 23:31
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 6

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 12 AUG 2020 17:11

PC Open Date & Time 12 AUG 2020 12:00

PC Close Date & Time 13 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 7

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.4 °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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 13 AUG 2020 14:44

PC Open Date & Time 13 AUG 2020 12:00

PC Close Date & Time 14 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 8

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	14 AUG 2020 21:18
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

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

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity
- Any use of prescription pain
reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity
- Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

07 AUG 2020 16:35

PC Open Date & Time

07 AUG 2020 16:24

PC Close Date & Time

07 AUG 2020 18:54

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

07 AUG 2020 22:37

PC Open Date & Time

07 AUG 2020 19:49

PC Close Date & Time

08 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 2

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

09 AUG 2020 00:33

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 3

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

09 AUG 2020 22:22

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 4

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

10 AUG 2020 13:05

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 5

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

11 AUG 2020 23:29

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 6

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

12 AUG 2020 17:10

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 7

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

13 AUG 2020 14:45

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

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

No
Yes

PC Time stamp	07 AUG 2020 16:37
PC Open Date & Time	07 AUG 2020 16:24
PC Close Date & Time	07 AUG 2020 18:54

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

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

No
Yes

PC Time stamp	07 AUG 2020 22:39
PC Open Date & Time	07 AUG 2020 19:49
PC Close Date & Time	08 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

	Yes <input type="checkbox"/>
PC Time stamp	09 AUG 2020 00:33
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

	Yes <input type="checkbox"/>
PC Time stamp	09 AUG 2020 22:23
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

	Yes <input type="checkbox"/>
PC Time stamp	10 AUG 2020 13:08
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

	Yes <input type="checkbox"/>
PC Time stamp	11 AUG 2020 23:28
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

	Yes <input type="checkbox"/>
PC Time stamp	13 AUG 2020 14:45
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

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

PC Time Stamp

14 AUG 2020 17:04

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

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

PC Time Stamp 15 AUG 2020 23:22

PC Open Date & Time 15 AUG 2020 12:00

PC Close Date & Time 16 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

FATIGUE

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time Stamp

14 AUG 2020 17:04

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

FATIGUE

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time Stamp

15 AUG 2020 23:22

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time stamp

14 AUG 2020 17:04

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

None

ACHES ALL OVER BODY

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time stamp 15 AUG 2020 23:23

PC Open Date & Time 15 AUG 2020 12:00

PC Close Date & Time 16 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	14 AUG 2020 17:04
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	15 AUG 2020 23:23
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3202057

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 19 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3202057

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3202057

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 20 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3202057

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3202057

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3202057

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:52:17

Generated On: 11 Aug 2021 22:05:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 01:52:17

Generated On: 11 Aug 2021 22:05:41

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	03 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	13:37 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 13:37
Temperature (<i>xxx.x</i>)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	76 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	58 mmHg
Diastolic Blood Pressure units	MMHG

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 01:52:17

Generated On: 11 Aug 2021 22:05:41

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	03 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	15:06 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 15:06
Temperature (<i>xxx.x</i>)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	67 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3202057

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:52:17

Generated On: 11 Aug 2021 22:05:41

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.

US3202057

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 13 Feb 2021 01:52:17

Generated On: 11 Aug 2021 22:05:41

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	03 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	03 SEP 2020
Collection time	13:20
Collection date and time (derived)	03 SEP 2020 13:20

US3202057

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

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) 3 SEP 2020

What was the treatment time? (00:00-23:59) 14:15 (24 HR)

Treatment Date and Time (derived) 3 SEP 2020 14:15

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

US3202057

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:52:17

Generated On: 11 Aug 2021 22:05:41

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 3 SEP 2020

Collection time (*00:00-23:59*) 13:51 (24 HR)

Collection date and time (derived) 3 SEP 2020 13:51

US3202057

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Collection date (<i>dd MMM yyyy</i>)			3 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:49	3 SEP 2020 13:49
Nasopharyngeal Swab 2	No		

US3202057

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.5 °F

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

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

PC Time Stamp 03 SEP 2020 14:44

PC Open Date & Time 03 SEP 2020 14:35

PC Close Date & Time 03 SEP 2020 17:05

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

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 03 SEP 2020 18:42
PC Open Date & Time 03 SEP 2020 18:00
PC Close Date & Time 04 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:05:41

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** 98.4 °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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 04 SEP 2020 18:10

PC Open Date & Time 04 SEP 2020 12:00

PC Close Date & Time 05 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:05:41

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

Please confirm reason for pain or fever medication (may select more than one):
To **TREAT** pain or fever that has already occurred
To **PREVENT** pain or fever from occurring
PC Time Stamp
PC Open Date & Time 05 SEP 2020 12:00
PC Close Date & Time 06 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:05:41

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	06 SEP 2020 22:45
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:05:41

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	07 SEP 2020 13:30
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:05:41

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	99.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	08 SEP 2020 14:33
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:41

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** 100.5 °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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 09 SEP 2020 19:46

PC Open Date & Time 09 SEP 2020 12:00

PC Close Date & Time 10 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 8

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

Please confirm reason for pain or fever medication (may select more than one):
To **TREAT** pain or fever that has already occurred _____
To **PREVENT** pain or fever from occurring _____
PC Time Stamp _____
PC Open Date & Time 10 SEP 2020 12:00
PC Close Date & Time 11 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 9

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Please confirm reason for pain or fever medication (may select more than one):	
To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False
PC Time Stamp	11 SEP 2020 13:49
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 10

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE in °F** 96.8 °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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 12 SEP 2020 20:30

PC Open Date & Time 12 SEP 2020 12:00

PC Close Date & Time 13 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 11

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.1 °F

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

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

PC Time Stamp 13 SEP 2020 18:58

PC Open Date & Time 13 SEP 2020 12:00

PC Close Date & Time 14 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

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	03 SEP 2020 14:41
PC Open Date & Time	03 SEP 2020 14:35
PC Close Date & Time	03 SEP 2020 17:05

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

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

03 SEP 2020 18:44

PC Open Date & Time

03 SEP 2020 18:00

PC Close Date & Time

04 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 2

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

04 SEP 2020 18:12

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 3

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

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

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

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

- Yes
- No

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

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

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 4

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 SEP 2020 22:47
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 5

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

07 SEP 2020 13:36

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 6

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	08 SEP 2020 14:35
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:05:41

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

09 SEP 2020 19:47

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

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

No

Yes

PC Time stamp	03 SEP 2020 14:41
PC Open Date & Time	03 SEP 2020 14:35
PC Close Date & Time	03 SEP 2020 17:05

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

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

No
Yes

PC Time stamp	03 SEP 2020 18:46
PC Open Date & Time	03 SEP 2020 18:00
PC Close Date & Time	04 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

	Yes <input type="checkbox"/>
PC Time stamp	04 SEP 2020 18:13
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

Yes

PC Time stamp

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

	Yes <input type="checkbox"/>
PC Time stamp	06 SEP 2020 22:49
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

	Yes <input type="checkbox"/>
PC Time stamp	07 SEP 2020 13:40
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

	Yes <input type="checkbox"/>
PC Time stamp	08 SEP 2020 14:36
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

	Yes <input type="checkbox"/>
PC Time stamp	09 SEP 2020 19:48
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

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

PC Time Stamp 10 SEP 2020 21:40

PC Open Date & Time 10 SEP 2020 12:00

PC Close Date & Time 11 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

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

PC Time Stamp

11 SEP 2020 13:48

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

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

PC Time Stamp 12 SEP 2020 20:31

PC Open Date & Time 12 SEP 2020 12:00

PC Close Date & Time 13 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(11)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

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

PC Time Stamp

13 SEP 2020 18:58

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

FATIGUE

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time Stamp

10 SEP 2020 21:40

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

FATIGUE

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time Stamp

11 SEP 2020 14:30

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

FATIGUE

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time Stamp

12 SEP 2020 20:31

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

FATIGUE

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time Stamp

13 SEP 2020 18:58

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="radio"/> Yes <input checked="" type="radio"/>
PC Time stamp	10 SEP 2020 21:41
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	11 SEP 2020 14:31
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	12 SEP 2020 20:31
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	13 SEP 2020 18:58
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3202057

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (dd MMM yyyy) 11 SEP 2020

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

Comments CONTACT ATTEMPTED 10 SEP
AND 11 SEP

If Contact Not Made, please provide Comments

US3202057

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3202057

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 18 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3202057

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3202057

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 24 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3202057

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3202057

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:52:17

Generated On: 11 Aug 2021 22:05:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3202057

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 01:52:17

Generated On: 11 Aug 2021 22:05:41

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	2 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	11:34 (24 HR)
Vital Signs Date and Time (derived)	2 OCT 2020 11:34
Temperature (<i>xxx.x</i>)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	70 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	101 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	64 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3202057

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:52:17

Generated On: 11 Aug 2021 22:05:41

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.

US3202057

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:52:17

Generated On: 11 Aug 2021 22:05:41

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 2 OCT 2020

Collection time (*00:00-23:59*) 11:48 (24 HR)

Collection date and time (derived) 2 OCT 2020 11:48

US3202057

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:52:17

Generated On: 11 Aug 2021 22:05:41

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	True
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	True
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 <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	07 OCT 2020 12:43:27
Patient Cloud Open Date & Time	07 OCT 2020 00:01
Patient Cloud Close Date & Time	11 OCT 2020 23:59

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	14 OCT 2020 07:24:02
Patient Cloud Open Date & Time	14 OCT 2020 00:01
Patient Cloud Close Date & Time	18 OCT 2020 23:59

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 OCT 2020 12:34:49
Patient Cloud Open Date & Time	21 OCT 2020 00:01
Patient Cloud Close Date & Time	25 OCT 2020 23:59

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 NOV 2020 15:07:45
Patient Cloud Open Date & Time	04 NOV 2020 00:01
Patient Cloud Close Date & Time	08 NOV 2020 23:59

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 99

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

No

Yes

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

No

Yes

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

Date and time of submission 13 NOV 2020 02:10:38

Patient Cloud Open Date & Time 11 NOV 2020 00:01

Patient Cloud Close Date & Time 15 NOV 2020 23:59

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 106

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

No

Yes

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

No

Yes

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

Date and time of submission 18 NOV 2020 14:16:46

Patient Cloud Open Date & Time 18 NOV 2020 00:01

Patient Cloud Close Date & Time 22 NOV 2020 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 110

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

No

Yes

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

No

Yes

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

Date and time of submission 25 NOV 2020 05:14:00

Patient Cloud Open Date & Time 22 NOV 2020 00:01

Patient Cloud Close Date & Time 26 NOV 2020 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 117

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

No

Yes

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

No

Yes

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

Date and time of submission 02 DEC 2020 09:28:31

Patient Cloud Open Date & Time 29 NOV 2020 00:01

Patient Cloud Close Date & Time 03 DEC 2020 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 DEC 2020 20:07:47
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 DEC 2020 14:38:18
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 DEC 2020 11:42:17
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 DEC 2020 16:18:35
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 152

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

No

Yes

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

No

Yes

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

Date and time of submission 05 JAN 2021 04:07:55

Patient Cloud Open Date & Time 03 JAN 2021 00:01

Patient Cloud Close Date & Time 07 JAN 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 JAN 2021 18:33:00
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 166

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

No

Yes

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

No

Yes

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

Date and time of submission 18 JAN 2021 23:02:28

Patient Cloud Open Date & Time 17 JAN 2021 00:01

Patient Cloud Close Date & Time 21 JAN 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 173

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

No

Yes

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

No

Yes

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

Date and time of submission 27 JAN 2021 06:25:59

Patient Cloud Open Date & Time 24 JAN 2021 00:01

Patient Cloud Close Date & Time 28 JAN 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 FEB 2021 23:33:28
Patient Cloud Open Date & Time	31 JAN 2021 00:01
Patient Cloud Close Date & Time	04 FEB 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 FEB 2021 12:20:37
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission 15 FEB 2021 15:41:24

Patient Cloud Open Date & Time 14 FEB 2021 00:01

Patient Cloud Close Date & Time 18 FEB 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 201

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

No

Yes

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

No

Yes

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

Date and time of submission 21 FEB 2021 08:49:21

Patient Cloud Open Date & Time 21 FEB 2021 00:01

Patient Cloud Close Date & Time 25 FEB 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 MAR 2021 02:15:54
Patient Cloud Open Date & Time	28 FEB 2021 00:01
Patient Cloud Close Date & Time	04 MAR 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 MAR 2021 02:56:18
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 222

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

No

Yes

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

No

Yes

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

Date and time of submission 15 MAR 2021 03:20:53

Patient Cloud Open Date & Time 14 MAR 2021 00:01

Patient Cloud Close Date & Time 18 MAR 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 MAR 2021 18:32:38
Patient Cloud Open Date & Time	21 MAR 2021 00:01
Patient Cloud Close Date & Time	25 MAR 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 MAR 2021 06:05:03
Patient Cloud Open Date & Time	28 MAR 2021 00:01
Patient Cloud Close Date & Time	01 APR 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 243

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

No

Yes

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

No

Yes

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

Date and time of submission 05 APR 2021 07:29:48

Patient Cloud Open Date & Time 04 APR 2021 00:01

Patient Cloud Close Date & Time 08 APR 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 APR 2021 09:23:13
Patient Cloud Open Date & Time	11 APR 2021 00:01
Patient Cloud Close Date & Time	15 APR 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 257

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

No

Yes

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

No

Yes

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

Date and time of submission

18 APR 2021 18:10:56

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	26 APR 2021 12:31:24
Patient Cloud Open Date & Time	25 APR 2021 00:01
Patient Cloud Close Date & Time	29 APR 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 271

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 285

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 320

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 327

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 334

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 341

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 348

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission	
Patient Cloud Open Date & Time	18 JUL 2021 00:01
Patient Cloud Close Date & Time	22 JUL 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 355

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 362

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 383

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 390

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 404

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

[Patient Cloud Close Date & Time](#) 16 SEP 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 411

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 418

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 425

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#) 07 OCT 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

Patient Cloud Open Date & Time	10 OCT 2021 00:01
Patient Cloud Close Date & Time	14 OCT 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 439

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

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

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

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

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

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

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

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 446

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

Patient Cloud Open Date & Time	24 OCT 2021 00:01
Patient Cloud Close Date & Time	28 OCT 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 460

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 467

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 474

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission	
Patient Cloud Open Date & Time	28 NOV 2021 00:01
Patient Cloud Close Date & Time	02 DEC 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 495

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

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

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

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

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

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

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

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission	
Patient Cloud Open Date & Time	12 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 509

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 516

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 530

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 544

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#) 03 FEB 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 551

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 558

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 565

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 572

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 593

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission	
Patient Cloud Open Date & Time	20 MAR 2022 00:01
Patient Cloud Close Date & Time	24 MAR 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 600

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

Patient Cloud Open Date & Time	03 APR 2022 00:01
Patient Cloud Close Date & Time	07 APR 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 614

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 621

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 628

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 635

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 642

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 649

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 656

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 663

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

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

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

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

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

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

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

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 670

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 677

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission	
Patient Cloud Open Date & Time	19 JUN 2022 00:01
Patient Cloud Close Date & Time	23 JUN 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 691

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

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07 JUL 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 705

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

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14 JUL 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 712

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 719

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

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28 JUL 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

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04 AUG 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 733

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 740

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

Patient Cloud Open Date & Time	14 AUG 2022 00:01
Patient Cloud Close Date & Time	18 AUG 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 747

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

Patient Cloud Open Date & Time	21 AUG 2022 00:01
Patient Cloud Close Date & Time	25 AUG 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

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08 SEP 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 789

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

Patient Cloud Open Date & Time	02 OCT 2022 00:01
Patient Cloud Close Date & Time	06 OCT 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 796

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3202057

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:05:41

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		02 MAR 2021 04:03:42

US3202057

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 12:38:09

Generated On: 11 Aug 2021 22:05:41

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 03 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3202057

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 12:38:09

Generated On: 11 Aug 2021 22:05:41

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3202057

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 13:28:16

Generated On: 11 Aug 2021 22:05:41

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 2 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3202057

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 13:28:16

Generated On: 11 Aug 2021 22:05:41

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3202057

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 13:28:16

Generated On: 11 Aug 2021 22:05:41

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 01 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3202057

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 13:28:16

Generated On: 11 Aug 2021 22:05:41

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3202057

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 13:28:16

Generated On: 11 Aug 2021 22:05:41

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 01 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3202057

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 13:28:16

Generated On: 11 Aug 2021 22:05:41

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3202057

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 13:28:16

Generated On: 11 Aug 2021 22:05:41

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 2 MAR 2021

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

Folder OID VISIT4

US3202057

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 13:28:16

Generated On: 11 Aug 2021 22:05:41

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3202057

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 13:28:16

Generated On: 11 Aug 2021 22:05:41

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.

US3202057

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 13:28:16

Generated On: 11 Aug 2021 22:05:41

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 2 MAR 2021

Collection time (*00:00-23:59*) 14:35 (24 HR)

Collection date and time (derived) 2 MAR 2021 14:35

US3202057

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 13:28:16

Generated On: 11 Aug 2021 22:05:41

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3202057

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

Was Contact Attempted? Yes
No

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

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

Comments _____

If Contact Not Made, please provide Comments _____

US3202057

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

Date of Contact	12 SEP 2020
Time of Contact	11:00
Date and Time of Contact (derived)	12 SEP 2020 11:00
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/> Clinical Visit - Unscheduled <input type="checkbox"/> Safety Call <input type="checkbox"/> Convalescent Tele-visit <input checked="" type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	9 SEP 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	10 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	37.2 C
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	11 SEP 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<hr/>
---------------	-------

O2 Saturation Units	<hr/>
---------------------	-------

Temperature	<hr/>
-------------	-------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

	Not Done <input type="checkbox"/>
Fatigue	None <input type="checkbox"/>
	Mild <input type="checkbox"/>
	Moderate <input type="checkbox"/>
	Severe <input type="checkbox"/>
	Not Done <input type="checkbox"/>
Muscle Aches (Myalgia)	None <input type="checkbox"/>
	Mild <input type="checkbox"/>
	Moderate <input type="checkbox"/>
	Severe <input type="checkbox"/>
	Not Done <input type="checkbox"/>
Body Aches	None <input type="checkbox"/>
	Mild <input type="checkbox"/>
	Moderate <input type="checkbox"/>
	Severe <input type="checkbox"/>
	Not Done <input type="checkbox"/>
Headache	None <input type="checkbox"/>
	Mild <input type="checkbox"/>
	Moderate <input type="checkbox"/>
	Severe <input type="checkbox"/>
	Not Done <input type="checkbox"/>
New Loss of Taste	None <input type="checkbox"/>
	Mild <input type="checkbox"/>
	Moderate <input type="checkbox"/>
	Severe <input type="checkbox"/>
	Not Done <input type="checkbox"/>
New Loss of Smell	None <input type="checkbox"/>
	Mild <input type="checkbox"/>
	Moderate <input type="checkbox"/>
	Severe <input type="checkbox"/>
	Not Done <input type="checkbox"/>

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	12 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	36.8 C
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 09 Apr 2021 13:28:13

Generated On: 11 Aug 2021 22:05:41

Date of Visit 10 SEP 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 10 SEP 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

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

[Generate Next COVID-19 Assessment](#)

Yes
No

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

Date of Contact	27 OCT 2020
Time of Contact	16:00
Date and Time of Contact (derived)	27 OCT 2020 16:00
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/> Clinical Visit - Unscheduled <input type="checkbox"/> Safety Call <input checked="" type="checkbox"/> Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

Symptom Day

Day 1	<input checked="" type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	24 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	25 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	96.8 F
-------------	--------

Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	26 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

	Not Done <input type="radio"/>
Fatigue	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Body Aches	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Headache	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Taste	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Smell	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	27 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	101.0 F
-------------	---------

Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

	Not Done <input type="radio"/>
Fatigue	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Body Aches	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Headache	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Taste	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Smell	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date 28 OCT 2020

Assessment Not Done False

O2 Saturation ND - Not Done

O2 Saturation Units %

Temperature 99.3 F

Chills

None	<input type="checkbox"/>
Mild	<input checked="" type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>
Not Done	<input type="checkbox"/>

Cough

None	<input type="checkbox"/>
Mild	<input checked="" type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>
Not Done	<input type="checkbox"/>

Shortness of Breath

None	<input checked="" type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>
Not Done	<input type="checkbox"/>

Difficulty Breathing

None	<input checked="" type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	29 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.0 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	30 OCT 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	_____
---------------	-------

O2 Saturation Units	_____
---------------------	-------

Temperature	_____
-------------	-------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date 31 OCT 2020

Assessment Not Done True

O2 Saturation _____

O2 Saturation Units _____

Temperature _____

Chills

None	<input type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>
Not Done	<input type="checkbox"/>

Cough

None	<input type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>
Not Done	<input type="checkbox"/>

Shortness of Breath

None	<input type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>
Not Done	<input type="checkbox"/>

Difficulty Breathing

None	<input type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

	Not Done <input type="checkbox"/>
Fatigue	None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Not Done <input type="checkbox"/>
Muscle Aches (Myalgia)	None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Not Done <input type="checkbox"/>
Body Aches	None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Not Done <input type="checkbox"/>
Headache	None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Not Done <input type="checkbox"/>
New Loss of Taste	None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Not Done <input type="checkbox"/>
New Loss of Smell	None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Not Done <input type="checkbox"/>

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date 1 NOV 2020

Assessment Not Done True

O2 Saturation _____

O2 Saturation Units _____

Temperature _____

Chills

None	<input type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>
Not Done	<input type="checkbox"/>

Cough

None	<input type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>
Not Done	<input type="checkbox"/>

Shortness of Breath

None	<input type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>
Not Done	<input type="checkbox"/>

Difficulty Breathing

None	<input type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

	Not Done <input type="radio"/>
Fatigue	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Body Aches	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Headache	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Taste	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Smell	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input checked="" type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	2 NOV 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.8 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

	Not Done <input type="radio"/>
Fatigue	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Body Aches	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Headache	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Taste	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Smell	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

Date of Visit 28 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 28 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

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

Visit	Was Saliva Collected?	Date of Collection
Day 3	NA (COVID-19 Negative)	
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)	

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	2 NOV 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) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 10 SEP 2020

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

Folder OID SICKD1

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	10 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	09:55 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 09:55
Temperature (<i>xxx.x</i>)	37.2 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	82 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3202057

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

10 SEP 2020

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

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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) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

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

Yes

No

NA (COVID-19 Negative)

Date of Collection

10 SEP 2020

US3202057

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 28 OCT 2020

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

Folder OID SICKD1

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	28 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	15:05 (24 HR)
Vital Signs Date and Time (derived)	28 OCT 2020 15:05
Temperature (<i>xxx.x</i>)	37.4 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	98 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	24 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	58 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3202057

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

28 OCT 2020

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

US3202057

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

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

Yes

No

NA (COVID-19 Negative)

Date of Collection

28 OCT 2020

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 13:28:13

Generated On: 11 Aug 2021 22:05:41

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) _____

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

Folder OID SICKD28

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 13:28:13

Generated On: 11 Aug 2021 22:05:41

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 13:28:13

Generated On: 11 Aug 2021 22:05:41

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.

US3202057

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 09 Apr 2021 13:28:06

Generated On: 11 Aug 2021 22:05:41

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

Yes

No

NA (COVID-19 Negative)

Date of Collection _____

US3202057

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

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 13:28:16

Generated On: 11 Aug 2021 22:05:41

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 5 JAN 2021

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

Folder OID UNBLND_DECIDE

US3202057

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

Form: Unblinding

Data signed: (b) (4) 22 Apr 2021 17:53:17

Generated On: 11 Aug 2021 22:05:41

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

US3202057

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 09 Apr 2021 13:28:16

Generated On: 11 Aug 2021 22:05:41

Height	164.0 cm
Weight	66.4 kg
BMI (xxx.x)	24.68769

US3202057

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Apr 2021 13:28:16

Generated On: 11 Aug 2021 22:05:41

Height	164.0 cm
Weight	66.4 kg
BMI (xxx.x)	24.68769
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	05 JAN 2021
Time of assessment (00:00-23:59)	14:42 (24 HR)
Vital Signs Date and Time (derived)	05 JAN 2021 14:42
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3202057

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Apr 2021 13:28:16

Generated On: 11 Aug 2021 22:05:41

Height	164.0 cm
Weight	66.4 kg
BMI (xxx.x)	24.68769
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 JAN 2021
Time of assessment (00:00-23:59)	17:29 (24 HR)
Vital Signs Date and Time (derived)	5 JAN 2021 17:29
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3202057

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

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

5 JAN 2021

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

US3202057

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

Form: Pregnancy Test

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

Was the pregnancy test performed? Yes
No

Date of test (dd MMM yyyy) 5 JAN 2021

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

Collection date _____
Collection time _____
Collection date and time (derived) _____

US3202057

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

Form: Exposure

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

Was study treatment given? Yes
No

If No, reason not given

Participant declined due to Adverse Event
Physician withheld dose due to Adverse Event
Death
Lost To Follow-Up
Physician Decision
Pregnancy
Protocol Deviation
Study Terminated by Sponsor
Withdrawal of Consent by Participant
Confirmed COVID-19
Other

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 5 JAN 2021

What was the treatment time? (00:00-23:59) 16:58 (24 HR)

Treatment Date and Time (derived) 5 JAN 2021 16:58

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

US3202057

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 5 JAN 2021

Collection time (*00:00-23:59*) 16:56 (24 HR)

Collection date and time (derived) 5 JAN 2021 16:56

US3202057

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 5 JAN 2021

Collection time (*00:00 - 23:59*) 16:54

Collection Date and Time (derived) 5 JAN 2021 16:54

US3202057

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

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3202057

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 13:28:16

Generated On: 11 Aug 2021 22:05:41

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 14 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3202057

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 13:28:16

Generated On: 11 Aug 2021 22:05:41

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3202057

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	2 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	13:50 (24 HR)
Vital Signs Date and Time (derived)	2 FEB 2021 13:50
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	76 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	2 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	14:35 (24 HR)
Vital Signs Date and Time (derived)	2 FEB 2021 14:35
Temperature (<i>xxx.x</i>)	37 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	78 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3202057

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

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.

US3202057

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

Was the pregnancy test performed? Yes
No

Date of test (dd MMM yyyy) 2 FEB 2021

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

Collection date _____

Collection time _____

Collection date and time (derived) _____

US3202057

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

Was study treatment given? Yes
No

If No, reason not given

Participant declined due to Adverse Event

Physician withheld dose due to Adverse Event

Death

Lost To Follow-Up

Physician Decision

Pregnancy

Protocol Deviation

Study Terminated by Sponsor

Withdrawal of Consent by Participant

Confirmed COVID-19

Other

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 2 FEB 2021

What was the treatment time? (00:00-23:59) 13:58 (24 HR)

Treatment Date and Time (derived) 2 FEB 2021 13:58

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

US3202057

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3202057

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 13:28:16

Generated On: 11 Aug 2021 22:05:41

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 13 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3202057

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 13:28:16

Generated On: 11 Aug 2021 22:05:41

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3202057

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3202057

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

Were vital signs assessed? Yes
No

Date of assessment (*dd MMM yyyy*) _____

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

Vital Signs Date and Time (derived) _____

Temperature (*xxx.x*) _____

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (*xxx*) _____

Pulse units _____

Respiratory Rate (*xxx*) _____

Respiratory Rate units _____

Systolic Blood Pressure (*xxx*) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (*xxx*) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3202057

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

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.

US3202057

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 2 MAR 2021

Collection time (*00:00-23:59*) 14:35 (24 HR)

Collection date and time (derived) 2 MAR 2021 14:35

US3202057

Folder: **Unscheduled (1)**

Form: **Unscheduled Visit Assessment**

Generated On: **11 Aug 2021 22:05:41**

Visit Date _____

Please check all assessments that apply for this visit

Physical Exam _____

Vital Signs _____

Immunogenicity Assessment _____

Pregnancy Test _____

US3202057

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 13:02:44

Generated On: 11 Aug 2021 22:05:41

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 17:53:17

Generated On: 11 Aug 2021 22:05:41

AEID	
Adverse event	HEADACHE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	07 AUG 2020
Start time (00:00-23:59)	16:00 (24 HR)
AE start date and time (derived)	07 AUG 2020 16:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	14 AUG 2020
End time (00:00-23:59)	08:00 (24 HR)
AE End Date and Time (derived)	14 AUG 2020 08:00
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 17:53:17

Generated On: 11 Aug 2021 22:05:41

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) 0

Admitted to ICU Derived (CSA Programming Field Only) _____

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 17:53:17

Generated On: 11 Aug 2021 22:05:41

AEID

Adverse event

UPPER RESPIRATORY
INFECTION (UNKNOWN
ETIOLOGY)

Was this a medically-attended AE? Yes
No

Was this a Solicited Adverse Reaction? Yes
No

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes
No

Start date (dd MMM yyyy) 09 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 14 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

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 17:53:17

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 17:53:17

Generated On: 11 Aug 2021 22:05:41

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	08 AUG 2020
Start time (00:00-23:59)	13:00 (24 HR)
AE start date and time (derived)	08 AUG 2020 13:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	14 AUG 2020
End time (00:00-23:59)	08:00 (24 HR)
AE End Date and Time (derived)	14 AUG 2020 08:00
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 17:53:17

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Apr 2021 17:53:17

Generated On: 11 Aug 2021 22:05:41

AEID	
Adverse event	MYALGIA (MUSCLE ACHES)
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	11 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	14 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Apr 2021 17:53:17

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Apr 2021 13:28:05

Generated On: 11 Aug 2021 22:05:41

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

Yes

No

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

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 13:28:04

Generated On: 11 Aug 2021 22:05:41

Name of Medication IBUPROFEN

Prophylaxis Yes
No

Indication HEADACHE

Dose per administration 800

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 13:28:04

Generated On: 11 Aug 2021 22:05:41

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (<i>dd MMM yyyy</i>)	13 AUG 2020
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If not Ongoing, End date (<i>dd MMM yyyy</i>)	13 AUG 2020
Was this medication taken for solicited event?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="checkbox"/> 803 <input type="checkbox"/> 804 <input checked="" type="checkbox"/>

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 13:28:04

Generated On: 11 Aug 2021 22:05:41

Name of Medication PROZAC

Prophylaxis Yes
No

Indication DEPRESSION

Dose per administration 40

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 13:28:04

Generated On: 11 Aug 2021 22:05:41

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 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) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 13:28:04

Generated On: 11 Aug 2021 22:05:41

Name of Medication TRAZADONE

Prophylaxis Yes
No

Indication ANXIETY

Dose per administration 10

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 13:28:04

Generated On: 11 Aug 2021 22:05:41

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN JUN 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) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 13:28:04

Generated On: 11 Aug 2021 22:05:41

Name of Medication IBUPROFEN

Prophylaxis Yes
No

Indication UPPER RESPIRATORY
INFECTION

Dose per administration 800

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 BID PRN
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 (4)

Data signed: (b) (4) 09 Apr 2021 13:28:04

Generated On: 11 Aug 2021 22:05:41

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 09 SEP 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 14 SEP 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

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 13:28:04

Generated On: 11 Aug 2021 22:05:41

Name of Medication TYLENOL

Prophylaxis Yes
No

Indication UPPER RESPIRATORY
INFECTION

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

BID PRN

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 13:28:04

Generated On: 11 Aug 2021 22:05:41

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 09 SEP 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 14 SEP 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

US3202057

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 13:28:05

Generated On: 11 Aug 2021 22:05:41

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3202057

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:05:41

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify)

SAE (specify)

Complete

Death

Lost To Follow-up

Physician decision (specify)

Pregnancy

Protocol deviation (specify)

Study Terminated By Sponsor

Withdrawal of consent by
participant (specify)

Other

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

If reason for discontinuation is Death, main cause of death

Adverse event

Unknown

Other

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes

No

Unknown

Audit

US3202057 (Prod: WR-ClinSearch, LLC)

US3202057

Form: Participant Creation

Generated On: 11 Aug 2021 22:05:41

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 21:33:16
User entered 'US3202057'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 17:59:30

US3202057

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	07 Aug 2020 20:18:17

US3202057

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '07 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 17:59:31

US3202057

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Clinic (Clinic)'	(b) (4) Tiffany Jewell (b) (4)	07 Aug 2020 20:18:17

US3202057

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User entered 'SCRN'	System	07 Aug 2020 20:18:17

US3202057

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:41

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered (b) (6) 1990' reason for change: Data Entry Error	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 22:29:13
User entered 'AUG 1990'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 17:59:32

US3202057

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:41

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '30'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:30:03
	(b) (4)	

US3202057

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:41

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User entered 'YEARS'	System	26 Aug 2020 19:30:03

US3202057

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:41

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User entered '30'	System	07 Aug 2020 20:18:33

US3202057

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:41

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Female (F)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:30:03
	(b) (4)	

US3202057

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:41

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:30:03
	(b) (4)	

US3202057

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:41

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '1'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:30:03
	(b) (4)	

US3202057

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:41

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '0'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:30:03
	(b) (4)	

US3202057

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:41

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '0'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:30:03
	(b) (4)	

US3202057

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:41

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '0'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:30:03
	(b) (4)	

US3202057

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:41

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '0'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:30:03
	(b) (4)	

US3202057

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:41

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '0'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:30:03
	(b) (4)	

US3202057

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:41

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered empty.	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:30:03
	(b) (4)	

US3202057

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:41

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '0'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:30:03
	(b) (4)	

US3202057

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:41

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '0'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:30:03
	(b) (4)	

US3202057

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:05:41

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:41:55
User entered '7 Aug 2020'	Tiffany Jewell (b) (4) (b) (4)	07 Aug 2020 20:18:33

US3202057

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:05:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User entered 'Aug 2020'	System	07 Aug 2020 20:18:33

US3202057

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:05:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User entered '2020'	System	07 Aug 2020 20:18:33

US3202057

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:05:41

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:41:55
User entered 'Amendment 1 (1)'	Tiffany Jewell (b) (4) (b) (4)	07 Aug 2020 20:18:33

US3202057

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:05:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:41:55
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	07 Aug 2020 20:18:33

US3202057

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:05:41

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:41:55
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	07 Aug 2020 20:18:33

US3202057

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:05:41

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:41:55
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	07 Aug 2020 20:18:33

US3202057

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:05:41

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:41:55
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	07 Aug 2020 20:18:33

US3202057

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:05:41

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:41:55
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 17:59:31

US3202057

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:05:41

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User entered '1'	System	07 Aug 2020 20:18:38

US3202057

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:05:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	07 Aug 2020 20:18:38

US3202057

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:05:41

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:30:21
	(b) (4)	

US3202057

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:05:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Disability issues, PT: Corrective lens user, LLT: Corrective lens user - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	19 Sep 2020 16:35:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 16:35:52
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Disability issues, PT: Corrective lens user, LLT: Contact lens wearer - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:09:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:09:27
Data point term sent to Coder	System	26 Aug 2020 19:30:47
User entered 'glasses/contacts'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 19:30:39

US3202057

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:05:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered empty.	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:30:39
	(b) (4)	

US3202057

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:05:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '1'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:30:39
	(b) (4)	

US3202057

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:05:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:30:39
	(b) (4)	

US3202057

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:05:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered empty.	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:30:39
	(b) (4)	

US3202057

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:05:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '0'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:30:39
	(b) (4)	

US3202057

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:05:41

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User entered empty.	System	26 Aug 2020 19:30:39

US3202057

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:05:41

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User entered empty.	System	26 Aug 2020 19:30:39

US3202057

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:05:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User entered empty.	System	26 Aug 2020 19:30:39

US3202057

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:05:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User entered empty.	System	26 Aug 2020 19:30:39

US3202057

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:05:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 18:09:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 18:09:37
Data point term sent to Coder	System	26 Aug 2020 19:31:49
User entered 'seasonal allergies'	zackery harmon (b) (4)	26 Aug 2020 19:30:59

US3202057

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:05:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered empty.	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:30:59
	(b) (4)	

US3202057

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:05:41

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '1'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:30:59
	(b) (4)	

US3202057

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:05:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:30:59
	(b) (4)	

US3202057

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:05:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered empty.	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:30:59
	(b) (4)	

US3202057

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:05:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '0'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:30:59
	(b) (4)	

US3202057

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:05:41

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User entered empty.	System	26 Aug 2020 19:30:59

US3202057

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:05:41

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User entered empty.	System	26 Aug 2020 19:30:59

US3202057

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:05:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User entered empty.	System	26 Aug 2020 19:30:59

US3202057

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:05:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User entered empty.	System	26 Aug 2020 19:30:59

US3202057

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:05:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
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)	27 Aug 2020 18:09:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 18:09:42
Data point term sent to Coder	System	26 Aug 2020 19:32:52
User entered 'Anxiety'	zackery harmon (b) (4)	26 Aug 2020 19:31:53
	(b) (4)	

US3202057

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:05:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'un UNK 2018'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:31:53
	(b) (4)	

US3202057

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:05:41

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '0'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:31:53
	(b) (4)	

US3202057

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:05:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Aug 2020 19:31:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 19:31:59
User entered 'Yes (Y)' reason for change: Data Entry Error	zackery harmon (b) (4)	26 Aug 2020 19:31:59
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Aug 2020 19:31:53
User entered empty.	System	26 Aug 2020 19:31:53
	zackery harmon (b) (4)	26 Aug 2020 19:31:53
	(b) (4)	

US3202057

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:05:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered empty.	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:31:53
	(b) (4)	

US3202057

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:05:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '0'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:31:53
	(b) (4)	

US3202057

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:05:41

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User entered 'Jan 2018'	System	26 Aug 2020 19:31:53

US3202057

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:05:41

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User entered '2018'	System	26 Aug 2020 19:31:53

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Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:05:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User entered empty.	System	26 Aug 2020 19:31:53

US3202057

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:05:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User entered empty.	System	26 Aug 2020 19:31:53

US3202057

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:05:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User coded data point as SOC: Psychiatric disorders, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 18:09:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 18:09:43
Data point term sent to Coder	System	26 Aug 2020 19:32:52
User entered 'Depression'	zackery harmon (b) (4)	26 Aug 2020 19:32:29

US3202057

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:05:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'un UNK 2018'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:32:29
	(b) (4)	

US3202057

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:05:41

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '0'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:32:29
	(b) (4)	

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Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:05:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:32:29
	(b) (4)	

US3202057

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:05:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered empty.	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:32:29
	(b) (4)	

US3202057

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:05:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '0'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:32:29
	(b) (4)	

US3202057

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:05:41

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User entered 'Jan 2018'	System	26 Aug 2020 19:32:29

US3202057

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:05:41

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User entered '2018'	System	26 Aug 2020 19:32:29

US3202057

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:05:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User entered empty.	System	26 Aug 2020 19:32:29

US3202057

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:05:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User entered empty.	System	26 Aug 2020 19:32:29

US3202057

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:05:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Urticaria, LLT: Hives - version MedDRA\23.0.	Coder Import (b) (4)	09 Sep 2020 12:54:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	09 Sep 2020 12:54:43
Data point term sent to Coder	System	26 Aug 2020 19:33:54
User entered 'Lyrica causes hives'	zackery harmon (b) (4)	26 Aug 2020 19:33:43
	(b) (4)	

US3202057

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:05:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'un UNK 2012'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:33:43
	(b) (4)	

US3202057

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:05:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '0'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:33:43
	(b) (4)	

US3202057

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:05:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:33:43
	(b) (4)	

US3202057

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:05:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered empty.	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:33:43
	(b) (4)	

US3202057

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:05:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '0'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:33:43
	(b) (4)	

US3202057

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:05:41

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User entered 'Jan 2012'	System	26 Aug 2020 19:33:43

US3202057

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:05:41

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User entered '2012'	System	26 Aug 2020 19:33:43

US3202057

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:05:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User entered empty.	System	26 Aug 2020 19:33:43

US3202057

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:05:41

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User entered empty.	System	26 Aug 2020 19:33:43

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:36:52
	(b) (4)	

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '07 Aug 2020'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:36:52
	(b) (4)	

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '14:17'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:36:52
	(b) (4)	

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User entered '07 Aug 2020 14:17'	System	26 Aug 2020 19:36:52

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '164.0' cm	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:36:52
DataPoint set to visible.	(b) (4) System	07 Aug 2020 20:18:38

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '67.1' kg	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:36:52
DataPoint set to visible.	(b) (4) System	07 Aug 2020 20:18:38

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
Amendment Manager: User entered '24.94795'	System	16 Sep 2020 23:47:46
User entered '24.9'	System	26 Aug 2020 19:36:52
DataPoint set to visible.	System	07 Aug 2020 20:18:38

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User entered 'kg/m2'	System	26 Aug 2020 19:36:52
DataPoint set to visible.	System	07 Aug 2020 20:18:38

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:36:52
	(b) (4)	

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered empty.	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:36:52
	(b) (4)	

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered empty.	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:36:52
	(b) (4)	

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:36:52
	(b) (4)	

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User entered 'bpm'	System	26 Aug 2020 19:36:52

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:36:52
	(b) (4)	

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User entered 'breaths/min'	System	26 Aug 2020 19:36:52

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:36:52
	(b) (4)	

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User entered 'mmHg'	System	26 Aug 2020 19:36:52

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:36:52
	(b) (4)	

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User entered 'mmHg'	System	26 Aug 2020 19:36:52

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15

US3202057

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:36:57
	(b) (4)	

US3202057

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered empty.	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:36:57
	(b) (4)	

US3202057

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:05:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '07 Aug 2020'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:37:12
	(b) (4)	

US3202057

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:05:41

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:37:12
	(b) (4)	

US3202057

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:05:41

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered empty.	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:37:12
	(b) (4)	

US3202057

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:05:41

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered empty.	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:37:12
	(b) (4)	

US3202057

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:05:41

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered empty.	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:37:12
	(b) (4)	

US3202057

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:05:41

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '0'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:37:12
	(b) (4)	

US3202057

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:05:41

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered empty.	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:37:12
	(b) (4)	

US3202057

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:05:41

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '0'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:37:12
	(b) (4)	

US3202057

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:17:12
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Jan 2021 21:15:18
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 19:37:21

US3202057

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:17:12
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Jan 2021 21:16:03
User entered '07 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Jan 2021 21:16:03
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Jan 2021 21:15:18
User entered empty.	zackery harmon (b) (4) (b) (4)	26 Aug 2020 19:37:21

US3202057

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:17:12
User entered 'Urine (URINE)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Jan 2021 21:15:18
User entered empty.	zackery harmon (b) (4) (b) (4)	26 Aug 2020 19:37:21

US3202057

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:17:12
User entered 'Negative (NEGATIVE)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Jan 2021 21:15:18
User entered empty.	zackery harmon (b) (4) (b) (4)	26 Aug 2020 19:37:21

US3202057

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:17:12
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Jan 2021 21:17:13
User entered empty.	zackery harmon (b) (4) (b) (4)	26 Aug 2020 19:37:21

US3202057

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:17:12
User entered '07 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Jan 2021 21:16:03
User entered empty.	zackery harmon (b) (4) (b) (4)	26 Aug 2020 19:37:21

US3202057

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:17:12
User entered '14:00' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Jan 2021 21:16:03
User entered empty.	zackery harmon (b) (4) (b) (4)	26 Aug 2020 19:37:21

US3202057

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User entered '07 Aug 2020 14:00'	System	18 Jan 2021 21:16:03
User entered empty.	System	26 Aug 2020 19:37:21

US3202057

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:41

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:37:52
	(b) (4)	

US3202057

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:41

[Emergency Response](#) (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:37:52
	(b) (4)	

US3202057

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:41

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)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:37:52
	(b) (4)	

US3202057

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:41

[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)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:37:52
	(b) (4)	

US3202057

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:41

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:37:52
	(b) (4)	

US3202057

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:41

[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)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:37:52
	(b) (4)	

US3202057

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:41

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)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:37:52
	(b) (4)	

US3202057

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:41

[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)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:37:52
	(b) (4)	

US3202057

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:41

[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)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:37:52
	(b) (4)	

US3202057

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:41

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)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:37:52
	(b) (4)	

US3202057

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:41

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)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:37:52
	(b) (4)	

US3202057

Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:37:52
	(b) (4)	

US3202057

Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered empty.	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:37:52
	(b) (4)	

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Folder: Screening

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '0'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:37:52
	(b) (4)	

US3202057

Folder: Screening

Form: Risk of Exposure

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[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '0'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:37:52
	(b) (4)	

US3202057

Folder: Screening

Form: Risk of Exposure

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[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)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '0'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:37:52
	(b) (4)	

US3202057

Folder: Screening

Form: Risk of Exposure

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[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)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '0'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:37:52
	(b) (4)	

US3202057

Folder: Screening

Form: Risk of Exposure

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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)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '0'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:37:52
	(b) (4)	

US3202057

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:41

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '1'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:37:52
	(b) (4)	

US3202057

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:41

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '0'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:37:52
	(b) (4)	

US3202057

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:41

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:52:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered empty.	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:37:52
	(b) (4)	

US3202057

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	07 Aug 2020 20:18:53

US3202057

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:52:15
User entered '07 Aug 2020' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	10 Nov 2020 19:14:39
User entered '7 Aug 2020'	Tiffany Jewell (b) (4) (b) (4)	07 Aug 2020 20:18:53

US3202057

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Clinic (Clinic)'	(b) (4) Tiffany Jewell (b) (4)	07 Aug 2020 20:18:53

US3202057

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered 'VISIT1'	System	07 Aug 2020 20:18:53

US3202057

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:05:41

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '07 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 18:14:28

US3202057

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:05:41

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 02:55:56
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:55:56
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Aug 2020 18:14:28
User entered '101985' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 18:14:28

US3202057

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:05:41

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 18:14:28

US3202057

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:05:41

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)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:38:44
	(b) (4)	

US3202057

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:05:41

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)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:38:44
	(b) (4)	

US3202057

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:05:41

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:38:44
	(b) (4)	

US3202057

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:05:41

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:38:44
	(b) (4)	

US3202057

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:05:41

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:38:44
	(b) (4)	

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:41

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:42:10
	(b) (4)	

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:41

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:42:10
	(b) (4)	

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:41

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:42:10
	(b) (4)	

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:41

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:42:10
	(b) (4)	

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User accepted default value 'Pre-Dose (PREDOSE)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 19:42:10

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:42:10
	(b) (4)	

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '07 Aug 2020'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:42:10
	(b) (4)	

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '14:17'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:42:10
	(b) (4)	

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered '07 Aug 2020 14:17'	System	26 Aug 2020 19:42:10

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '36.6' C	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:42:10
	(b) (4)	

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Oral (Oral)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:42:10
	(b) (4)	

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered empty.	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:42:10
	(b) (4)	

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '83'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:42:10
	(b) (4)	

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered 'bpm'	System	26 Aug 2020 19:42:10

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '14'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:42:10
	(b) (4)	

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered 'breaths/min'	System	26 Aug 2020 19:42:10

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '100'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:42:10
	(b) (4)	

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered 'mmHg'	System	26 Aug 2020 19:42:10

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '66'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:42:10
	(b) (4)	

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered 'mmHg'	System	26 Aug 2020 19:42:10

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:41

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:42:10
	(b) (4)	

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:41

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:42:10
	(b) (4)	

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User accepted default value 'Post-Dose (POSTDOSE)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 19:42:10

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:42:10
	(b) (4)	

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '07 Aug 2020'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:42:10
	(b) (4)	

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '16:35'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:42:10
	(b) (4)	

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered '07 Aug 2020 16:35'	System	26 Aug 2020 19:42:10

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '36.6' C	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:42:10
	(b) (4)	

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Oral (Oral)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:42:10
	(b) (4)	

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered empty.	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:42:10
	(b) (4)	

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '91'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:42:10
	(b) (4)	

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered 'bpm'	System	26 Aug 2020 19:42:10

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '14'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:42:10
	(b) (4)	

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered 'breaths/min'	System	26 Aug 2020 19:42:10

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '103'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:42:10
	(b) (4)	

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered 'mmHg'	System	26 Aug 2020 19:42:10

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '69'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:42:10

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered 'mmHg'	System	26 Aug 2020 19:42:10

US3202057

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:38:55
	(b) (4)	

US3202057

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '07 Aug 2020'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:38:55
	(b) (4)	

US3202057

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:16:58
User closed query 'per eDC guidelines please enter details under screening and enter "no" under V1 if done the same date, please verify' (Site from CRA).	(b) (4), (b) (6)	19 Jan 2021 19:16:39
Query 'per eDC guidelines please enter details under screening and enter "no" under V1 if done the same date, please verify' answered with 'CORRECTED' (Site from CRA).	(b) (4), (b) (6)	18 Jan 2021 21:17:02
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Jan 2021 21:16:48
User opened query 'per eDC guidelines please enter details under screening and enter "no" under V1 if done the same date, please verify' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 14:25:23
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 19:39:25

US3202057

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:16:58
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	18 Jan 2021 21:16:48
User entered '07 Aug 2020'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 19:39:25

US3202057

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:16:58
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	18 Jan 2021 21:16:48
User entered 'Urine (URINE)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 19:39:25

US3202057

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:16:58
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	18 Jan 2021 21:16:48
User entered 'Negative (NEGATIVE)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 19:39:25

US3202057

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:16:58
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	18 Jan 2021 21:16:48
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 19:39:25

US3202057

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:16:58
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	18 Jan 2021 21:16:48
User entered '07 Aug 2020'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 19:39:25

US3202057

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:16:58
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	18 Jan 2021 21:16:48
User entered '14:00'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 19:39:25

US3202057

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered empty.	System	18 Jan 2021 21:16:48
User entered '07 Aug 2020 14:00'	System	26 Aug 2020 19:39:25

US3202057

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	07 Aug 2020 20:19:38

US3202057

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	07 Aug 2020 20:19:38

US3202057

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

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)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	07 Aug 2020 20:19:38
	(b) (4)	

US3202057

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered 'MRNA-1273 OR PLACEBO'	System	07 Aug 2020 20:19:38

US3202057

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '7 Aug 2020'	(b) (4) Tiffany Jewell (b) (4)	07 Aug 2020 20:19:38

US3202057

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '16:04'	(b) (4) Tiffany Jewell (b) (4)	07 Aug 2020 20:19:38

US3202057

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered '7 Aug 2020 16:04'	System	07 Aug 2020 20:19:38

US3202057

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Left Arm (LEFT ARM)'	(b) (4) Tiffany Jewell (b) (4)	07 Aug 2020 20:19:38

US3202057

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered 'ONCE'	System	07 Aug 2020 20:19:38

US3202057

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered 'INTRAMUSCULAR'	System	07 Aug 2020 20:19:38

US3202057

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:39:38
	(b) (4)	

US3202057

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '07 Aug 2020'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:39:38
	(b) (4)	

US3202057

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '14:34'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:39:38
	(b) (4)	

US3202057

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered '07 Aug 2020 14:34'	System	26 Aug 2020 19:39:38

US3202057

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:05:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '07 Aug 2020'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:40:21
	(b) (4)	

US3202057

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:05:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 19:40:21

US3202057

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:05:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:40:21
	(b) (4)	

US3202057

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:05:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '14:32'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:40:21
	(b) (4)	

US3202057

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:05:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered '07 Aug 2020 14:32'	System	26 Aug 2020 19:40:21

US3202057

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:05:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 19:40:21

US3202057

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:05:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:40:36
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 19:40:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 19:40:27
User entered 'Yes (Y)' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	26 Aug 2020 19:40:27
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 19:40:21
User entered empty.	zackery harmon (b) (4) (b) (4)	26 Aug 2020 19:40:21

US3202057

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:05:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	(b) (4)	26 Aug 2020 19:40:36
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	26 Aug 2020 19:40:36
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	26 Aug 2020 19:40:27
User entered empty.	zackery harmon (b) (4)	26 Aug 2020 19:40:21
	(b) (4)	

US3202057

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:05:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered empty.	System	26 Aug 2020 19:40:21

US3202057

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Yes (Y)'	Lilian Nukuna (b) (4)	19 Aug 2020 14:11:48

US3202057

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered '1'	System	19 Aug 2020 14:11:48

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T16:37:45', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '019245ac-c745-4db9-a038-65f2c14cd49a'	System	07 Aug 2020 20:38:11
User entered 'Yes (Y)'	System	07 Aug 2020 20:38:11

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T16:37:55', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '019245ac-c745-4db9-a038-65f2c14cd49a'	System	07 Aug 2020 20:38:11
User entered '97.1'	System	07 Aug 2020 20:38:11

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T16:38:01', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '019245ac-c745-4db9-a038-65f2c14cd49a'	System	07 Aug 2020 20:38:11
User entered 'No (N)'	System	07 Aug 2020 20:38:11

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T16:38:06', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '019245ac-c745-4db9-a038-65f2c14cd49a'	System	07 Aug 2020 20:38:11
User entered '07 Aug 2020 16:38'	System	07 Aug 2020 20:38:11

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '07 Aug 2020 16:24'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '07 Aug 2020 18:54'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T22:36:31', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '4884788e-2a60-4966-bf22-d64d2458ba50'	System	08 Aug 2020 02:37:05
User entered 'Yes (Y)'	System	08 Aug 2020 02:37:05

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T22:36:38', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '4884788e-2a60-4966-bf22-d64d2458ba50'	System	08 Aug 2020 02:37:05
User entered '97.3'	System	08 Aug 2020 02:37:05

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T22:36:57', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '4884788e-2a60-4966-bf22-d64d2458ba50'	System	08 Aug 2020 02:37:05
User entered 'No (N)'	System	08 Aug 2020 02:37:05

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T22:37:03', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '4884788e-2a60-4966-bf22-d64d2458ba50'	System	08 Aug 2020 02:37:05
User entered '07 Aug 2020 22:37'	System	08 Aug 2020 02:37:05

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '07 Aug 2020 19:49'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered 'Day 2'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T00:32:12', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ff997994-46d7-42a2-87f7-da44c573ce4c'	System	09 Aug 2020 04:32:37
User entered 'Yes (Y)'	System	09 Aug 2020 04:32:37

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T00:32:21', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ff997994-46d7-42a2-87f7-da44c573ce4c'	System	09 Aug 2020 04:32:37
User entered '98.1'	System	09 Aug 2020 04:32:37

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:05:41

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T00:32:26', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ff997994-46d7-42a2-87f7-da44c573ce4c'	System	09 Aug 2020 04:32:37
User entered 'No (N)'	System	09 Aug 2020 04:32:37

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T00:32:32', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ff997994-46d7-42a2-87f7-da44c573ce4c'	System	09 Aug 2020 04:32:37
User entered '09 Aug 2020 00:32'	System	09 Aug 2020 04:32:37

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered 'Day 3'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T22:20:45', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'a94d34b4-8158-454e-b954-8ef706738f52'	System	10 Aug 2020 02:20:57
User entered 'Yes (Y)'	System	10 Aug 2020 02:20:57

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T22:20:49', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'a94d34b4-8158-454e-b954-8ef706738f52'	System	10 Aug 2020 02:20:57
User entered '97.7'	System	10 Aug 2020 02:20:57

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:05:41

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T22:20:52', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'a94d34b4-8158-454e-b954-8ef706738f52'	System	10 Aug 2020 02:20:57
User entered 'No (N)'	System	10 Aug 2020 02:20:57

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T22:20:55', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'a94d34b4-8158-454e-b954-8ef706738f52'	System	10 Aug 2020 02:20:57
User entered '09 Aug 2020 22:20'	System	10 Aug 2020 02:20:57

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered 'Day 4'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-10T13:35:31', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9f3f967f-a57f-4b87-b2b2-4dbcd92fb8c7'	System	10 Aug 2020 17:35:47
User entered 'Yes (Y)'	System	10 Aug 2020 17:35:47

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-10T13:35:37', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9f3f967f-a57f-4b87-b2b2-4dbcd92fb8c7'	System	10 Aug 2020 17:35:47
User entered '98.1'	System	10 Aug 2020 17:35:47

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:05:41

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-10T13:35:41', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9f3f967f-a57f-4b87-b2b2-4dbcd92fb8c7'	System	10 Aug 2020 17:35:47
User entered 'No (N)'	System	10 Aug 2020 17:35:47

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-10T13:35:45', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9f3f967f-a57f-4b87-b2b2-4dbcd92fb8c7'	System	10 Aug 2020 17:35:47
User entered '10 Aug 2020 13:35'	System	10 Aug 2020 17:35:47

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered 'Day 5'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-11T23:31:20', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'b6aa31a9-ec88-4679-a4de-741bf1d46a8d'	System	12 Aug 2020 03:31:44
User entered 'Yes (Y)'	System	12 Aug 2020 03:31:44

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-11T23:31:25', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'b6aa31a9-ec88-4679-a4de-741bf1d46a8d'	System	12 Aug 2020 03:31:44
User entered '97.1'	System	12 Aug 2020 03:31:44

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:05:41

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-11T23:31:39', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'b6aa31a9-ec88-4679-a4de-741bf1d46a8d'	System	12 Aug 2020 03:31:44
User entered 'No (N)'	System	12 Aug 2020 03:31:44

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-11T23:31:43', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'b6aa31a9-ec88-4679-a4de-741bf1d46a8d'	System	12 Aug 2020 03:31:44
User entered '11 Aug 2020 23:31'	System	12 Aug 2020 03:31:44

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered 'Day 6'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-12T17:10:36', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ae22f254-5fad-4b3c-a86a-f7b7d57f564e'	System	12 Aug 2020 21:11:17
User entered 'Yes (Y)'	System	12 Aug 2020 21:11:17

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-12T17:10:45', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ae22f254-5fad-4b3c-a86a-f7b7d57f564e'	System	12 Aug 2020 21:11:17
User entered '97.9'	System	12 Aug 2020 21:11:17

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:05:41

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-12T17:11:04', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ae22f254-5fad-4b3c-a86a-f7b7d57f564e'	System	12 Aug 2020 21:11:17
User entered 'Yes (Y)'	System	12 Aug 2020 21:11:17

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:05:41

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'spoke with subject and she confirmed she had experienced a headache for the following day after the vaccination. She did take motrin 800mg twice on that day.' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 17:33:46
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Lilian Nukuna (b) (4) (b) (4)	19 Aug 2020 13:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-12T17:11:11', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ae22f254-5fad-4b3c-a86a-f7b7d57f564e'	System	12 Aug 2020 21:11:17
User entered '1'	System	12 Aug 2020 21:11:17

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:05:41

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-12T17:11:11', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ae22f254-5fad-4b3c-a86a-f7b7d57f564e'	System	12 Aug 2020 21:11:17
User entered '0'	System	12 Aug 2020 21:11:17

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-12T17:11:14', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ae22f254-5fad-4b3c-a86a-f7b7d57f564e' User entered '12 Aug 2020 17:11'	System	12 Aug 2020 21:11:17
	System	12 Aug 2020 21:11:17

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered 'Day 7'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-13T14:44:19', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f577aa3e-b33b-45c9-815d-39ab43461d92'	System	13 Aug 2020 18:44:48
User entered 'Yes (Y)'	System	13 Aug 2020 18:44:48

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-13T14:44:25', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f577aa3e-b33b-45c9-815d-39ab43461d92'	System	13 Aug 2020 18:44:48
User entered '97.4'	System	13 Aug 2020 18:44:48

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:41

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-13T14:44:35', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f577aa3e-b33b-45c9-815d-39ab43461d92'	System	13 Aug 2020 18:44:48
User entered 'Yes (Y)'	System	13 Aug 2020 18:44:48

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:41

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'spoke with subject she indicated that. she took motrin 800mg for a headache which she had post vaccination. She also stated that she has migraines intermittently which are not vaccine related.' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 17:33:58
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Lilian Nukuna (b) (4) (b) (4)	19 Aug 2020 13:38:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-13T14:44:43', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f577aa3e-b33b-45c9-815d-39ab43461d92'	System	13 Aug 2020 18:44:48
User entered '1'	System	13 Aug 2020 18:44:48

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:41

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-13T14:44:43', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f577aa3e-b33b-45c9-815d-39ab43461d92'	System	13 Aug 2020 18:44:48
User entered '0'	System	13 Aug 2020 18:44:48

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-13T14:44:46', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f577aa3e-b33b-45c9-815d-39ab43461d92'	System	13 Aug 2020 18:44:48
User entered '13 Aug 2020 14:44'	System	13 Aug 2020 18:44:48

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	12 Aug 2020 21:11:17
User entered 'Day 8'	System	12 Aug 2020 21:11:17

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-14T21:18:24', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ee727f3c-ca64-4e32-96fe-25605a333af7'	System	15 Aug 2020 01:18:48
User entered 'Yes (Y)'	System	15 Aug 2020 01:18:48

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-14T21:18:34', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ee727f3c-ca64-4e32-96fe-25605a333af7'	System	15 Aug 2020 01:18:48
User entered '97.3'	System	15 Aug 2020 01:18:48

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:05:41

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-14T21:18:38', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ee727f3c-ca64-4e32-96fe-25605a333af7'	System	15 Aug 2020 01:18:48
User entered 'No (N)'	System	15 Aug 2020 01:18:48

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-14T21:18:42', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ee727f3c-ca64-4e32-96fe-25605a333af7'	System	15 Aug 2020 01:18:48
User entered '14 Aug 2020 21:18'	System	15 Aug 2020 01:18:48

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 21:11:17

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 21:11:17

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T16:34:22', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1526f1ab-8f49-4944-ab9f-1df0b55afbdf'	System	07 Aug 2020 20:35:19
User entered 'Does not interfere with activity (2)'	System	07 Aug 2020 20:35:19

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T16:34:28', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1526f1ab-8f49-4944-ab9f-1df0b55afbfd'	System	07 Aug 2020 20:35:19
User entered 'No (N)'	System	07 Aug 2020 20:35:19

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T16:34:35', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1526f1ab-8f49-4944-ab9f-1df0b55afbfd'	System	07 Aug 2020 20:35:19
User entered 'No (N)'	System	07 Aug 2020 20:35:19

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T16:35:02', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1526f1ab-8f49-4944-ab9f-1df0b55afbfd'	System	07 Aug 2020 20:35:19
User entered 'None (1)'	System	07 Aug 2020 20:35:19

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T16:35:16', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1526f1ab-8f49-4944-ab9f-1df0b55afbfd'	System	07 Aug 2020 20:35:19
User entered '07 Aug 2020 16:35'	System	07 Aug 2020 20:35:19

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '07 Aug 2020 16:24'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '07 Aug 2020 18:54'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T22:37:21', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '08face81-58fb-4e94-83a2-07e7b75420d0'	System	08 Aug 2020 02:37:47
User entered 'None (1)'	System	08 Aug 2020 02:37:47

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T22:37:28', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '08face81-58fb-4e94-83a2-07e7b75420d0'	System	08 Aug 2020 02:37:47
User entered 'No (N)'	System	08 Aug 2020 02:37:47

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T22:37:34', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '08face81-58fb-4e94-83a2-07e7b75420d0'	System	08 Aug 2020 02:37:47
User entered 'No (N)'	System	08 Aug 2020 02:37:47

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T22:37:39', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '08face81-58fb-4e94-83a2-07e7b75420d0'	System	08 Aug 2020 02:37:47
User entered 'None (1)'	System	08 Aug 2020 02:37:47

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T22:37:45', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '08face81-58fb-4e94-83a2-07e7b75420d0'	System	08 Aug 2020 02:37:47
User entered '07 Aug 2020 22:37'	System	08 Aug 2020 02:37:47

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '07 Aug 2020 19:49'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered 'Day 2'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:05:41

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T00:32:42', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ccaf4e42-b8e2-4285-a4bf-5e8e684bb567'	System	09 Aug 2020 04:33:18
User entered 'None (1)'	System	09 Aug 2020 04:33:18

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:05:41

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T00:32:51', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ccaf4e42-b8e2-4285-a4bf-5e8e684bb567'	System	09 Aug 2020 04:33:18
User entered 'No (N)'	System	09 Aug 2020 04:33:18

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:05:41

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T00:32:57', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ccaf4e42-b8e2-4285-a4bf-5e8e684bb567'	System	09 Aug 2020 04:33:18
User entered 'No (N)'	System	09 Aug 2020 04:33:18

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:05:41

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T00:33:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ccaf4e42-b8e2-4285-a4bf-5e8e684bb567'	System	09 Aug 2020 04:33:18
User entered 'None (1)'	System	09 Aug 2020 04:33:18

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T00:33:12', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ccaf4e42-b8e2-4285-a4bf-5e8e684bb567'	System	09 Aug 2020 04:33:18
User entered '09 Aug 2020 00:33'	System	09 Aug 2020 04:33:18

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered 'Day 3'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:41

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T22:21:47', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f6e828ed-72e3-49de-89f2-4cd548f83a05'	System	10 Aug 2020 02:22:06
User entered 'None (1)'	System	10 Aug 2020 02:22:06

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:41

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T22:21:50', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f6e828ed-72e3-49de-89f2-4cd548f83a05'	System	10 Aug 2020 02:22:06
User entered 'No (N)'	System	10 Aug 2020 02:22:06

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:41

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T22:21:53', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f6e828ed-72e3-49de-89f2-4cd548f83a05'	System	10 Aug 2020 02:22:06
User entered 'No (N)'	System	10 Aug 2020 02:22:06

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:41

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T22:21:59', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f6e828ed-72e3-49de-89f2-4cd548f83a05'	System	10 Aug 2020 02:22:06
User entered 'None (1)'	System	10 Aug 2020 02:22:06

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T22:22:03', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f6e828ed-72e3-49de-89f2-4cd548f83a05'	System	10 Aug 2020 02:22:06
User entered '09 Aug 2020 22:22'	System	10 Aug 2020 02:22:06

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered 'Day 4'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:05:41

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-10T13:04:36', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '16f593e8-d690-4ca2-9104-dfa94359ab13'	System	10 Aug 2020 17:05:32
User entered 'None (1)'	System	10 Aug 2020 17:05:32

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:05:41

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-10T13:05:08', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '16f593e8-d690-4ca2-9104-dfa94359ab13'	System	10 Aug 2020 17:05:32
User entered 'No (N)'	System	10 Aug 2020 17:05:32

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:05:41

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-10T13:05:12', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '16f593e8-d690-4ca2-9104-dfa94359ab13'	System	10 Aug 2020 17:05:32
User entered 'No (N)'	System	10 Aug 2020 17:05:32

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:05:41

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-10T13:05:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '16f593e8-d690-4ca2-9104-dfa94359ab13'	System	10 Aug 2020 17:05:32
User entered 'None (1)'	System	10 Aug 2020 17:05:32

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-10T13:05:28', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '16f593e8-d690-4ca2-9104-dfa94359ab13'	System	10 Aug 2020 17:05:32
User entered '10 Aug 2020 13:05'	System	10 Aug 2020 17:05:32

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered 'Day 5'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:41

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-11T23:28:39', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'faf2a272-a62a-40b5-ab9d-b9a7d606f3e4'	System	12 Aug 2020 03:29:25
User entered 'None (1)'	System	12 Aug 2020 03:29:25

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:41

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-11T23:29:04', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'faf2a272-a62a-40b5-ab9d-b9a7d606f3e4'	System	12 Aug 2020 03:29:25
User entered 'No (N)'	System	12 Aug 2020 03:29:25

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:41

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-11T23:29:07', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'faf2a272-a62a-40b5-ab9d-b9a7d606f3e4'	System	12 Aug 2020 03:29:25
User entered 'No (N)'	System	12 Aug 2020 03:29:25

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:41

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-11T23:29:10', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'faf2a272-a62a-40b5-ab9d-b9a7d606f3e4'	System	12 Aug 2020 03:29:25
User entered 'None (1)'	System	12 Aug 2020 03:29:25

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-11T23:29:23', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'faf2a272-a62a-40b5-ab9d-b9a7d606f3e4'	System	12 Aug 2020 03:29:25
User entered '11 Aug 2020 23:29'	System	12 Aug 2020 03:29:25

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered 'Day 6'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:05:41

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-12T17:09:53', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1e6503dd-26f0-4029-8aab-3a162fd8b983'	System	12 Aug 2020 21:10:21
User entered 'None (1)'	System	12 Aug 2020 21:10:21

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:05:41

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-12T17:09:55', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1e6503dd-26f0-4029-8aab-3a162fd8b983'	System	12 Aug 2020 21:10:21
User entered 'No (N)'	System	12 Aug 2020 21:10:21

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:05:41

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-12T17:09:57', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1e6503dd-26f0-4029-8aab-3a162fd8b983'	System	12 Aug 2020 21:10:21
User entered 'No (N)'	System	12 Aug 2020 21:10:21

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:05:41

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-12T17:10:01', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1e6503dd-26f0-4029-8aab-3a162fd8b983'	System	12 Aug 2020 21:10:21
User entered 'None (1)'	System	12 Aug 2020 21:10:21

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-12T17:10:05', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1e6503dd-26f0-4029-8aab-3a162fd8b983'	System	12 Aug 2020 21:10:21
User entered '12 Aug 2020 17:10'	System	12 Aug 2020 21:10:21

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered 'Day 7'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:05:41

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-13T14:44:50', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '35c0c2c8-fd82-4648-8507-d5c4affa0ea0'	System	13 Aug 2020 18:45:06
User entered 'None (1)'	System	13 Aug 2020 18:45:06

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:05:41

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-13T14:44:53', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '35c0c2c8-fd82-4648-8507-d5c4affa0ea0'	System	13 Aug 2020 18:45:06
User entered 'No (N)'	System	13 Aug 2020 18:45:06

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:05:41

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-13T14:44:56', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '35c0c2c8-fd82-4648-8507-d5c4affa0ea0'	System	13 Aug 2020 18:45:06
User entered 'No (N)'	System	13 Aug 2020 18:45:06

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:05:41

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-13T14:44:59', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '35c0c2c8-fd82-4648-8507-d5c4affa0ea0'	System	13 Aug 2020 18:45:06
User entered 'None (1)'	System	13 Aug 2020 18:45:06

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-13T14:45:03', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '35c0c2c8-fd82-4648-8507-d5c4affa0ea0' User entered '13 Aug 2020 14:45'	System	13 Aug 2020 18:45:06
	System	13 Aug 2020 18:45:06

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T16:36:07', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '0d80b3eb-4e09-4953-9087-e3bd07f58d92'	System	07 Aug 2020 20:37:16
User entered 'None (0)'	System	07 Aug 2020 20:37:16

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T16:36:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '0d80b3eb-4e09-4953-9087-e3bd07f58d92'	System	07 Aug 2020 20:37:16
User entered 'None (0)'	System	07 Aug 2020 20:37:16

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T16:36:19', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '0d80b3eb-4e09-4953-9087-e3bd07f58d92'	System	07 Aug 2020 20:37:16
User entered 'None (0)'	System	07 Aug 2020 20:37:16

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T16:36:23', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '0d80b3eb-4e09-4953-9087-e3bd07f58d92'	System	07 Aug 2020 20:37:16
User entered 'None (0)'	System	07 Aug 2020 20:37:16

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T16:36:32', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '0d80b3eb-4e09-4953-9087-e3bd07f58d92'	System	07 Aug 2020 20:37:16
User entered 'None (0)'	System	07 Aug 2020 20:37:16

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T16:36:52', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '0d80b3eb-4e09-4953-9087-e3bd07f58d92'	System	07 Aug 2020 20:37:16
User entered 'None (0)'	System	07 Aug 2020 20:37:16

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

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)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T16:37:07', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '0d80b3eb-4e09-4953-9087-e3bd07f58d92'	System	07 Aug 2020 20:37:16
User entered 'No (N)'	System	07 Aug 2020 20:37:16

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T16:37:12', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '0d80b3eb-4e09-4953-9087-e3bd07f58d92'	System	07 Aug 2020 20:37:16
User entered '07 Aug 2020 16:37'	System	07 Aug 2020 20:37:16

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '07 Aug 2020 16:24'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '07 Aug 2020 18:54'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T22:38:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9c9465f3-e052-4436-a6b2-3c9412577da0'	System	08 Aug 2020 02:39:07
User entered 'No interference with activity (1)'	System	08 Aug 2020 02:39:07

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T22:38:05', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9c9465f3-e052-4436-a6b2-3c9412577da0'	System	08 Aug 2020 02:39:07
User entered 'None (0)'	System	08 Aug 2020 02:39:07

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T22:38:12', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9c9465f3-e052-4436-a6b2-3c9412577da0'	System	08 Aug 2020 02:39:07
User entered 'None (0)'	System	08 Aug 2020 02:39:07

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T22:38:18', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9c9465f3-e052-4436-a6b2-3c9412577da0'	System	08 Aug 2020 02:39:07
User entered 'None (0)'	System	08 Aug 2020 02:39:07

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T22:38:31', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9c9465f3-e052-4436-a6b2-3c9412577da0'	System	08 Aug 2020 02:39:07
User entered 'None (0)'	System	08 Aug 2020 02:39:07

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T22:38:42', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9c9465f3-e052-4436-a6b2-3c9412577da0'	System	08 Aug 2020 02:39:07
User entered 'None (0)'	System	08 Aug 2020 02:39:07

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

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)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T22:39:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9c9465f3-e052-4436-a6b2-3c9412577da0'	System	08 Aug 2020 02:39:07
User entered 'No (N)'	System	08 Aug 2020 02:39:07

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T22:39:03', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9c9465f3-e052-4436-a6b2-3c9412577da0'	System	08 Aug 2020 02:39:07
User entered '07 Aug 2020 22:39'	System	08 Aug 2020 02:39:07

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '07 Aug 2020 19:49'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered 'Day 2'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T00:33:20', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '6004e5c1-089f-46f5-a1ae-6ee6f7c2da06'	System	09 Aug 2020 04:34:05
User entered 'No interference with activity (1)'	System	09 Aug 2020 04:34:05

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T00:33:27', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '6004e5c1-089f-46f5-a1ae-6ee6f7c2da06'	System	09 Aug 2020 04:34:05
User entered 'No interference with activity (1)'	System	09 Aug 2020 04:34:05

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T00:33:33', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '6004e5c1-089f-46f5-a1ae-6ee6f7c2da06'	System	09 Aug 2020 04:34:05
User entered 'None (0)'	System	09 Aug 2020 04:34:05

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T00:33:35', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '6004e5c1-089f-46f5-a1ae-6ee6f7c2da06'	System	09 Aug 2020 04:34:05
User entered 'None (0)'	System	09 Aug 2020 04:34:05

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T00:33:38', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '6004e5c1-089f-46f5-a1ae-6ee6f7c2da06'	System	09 Aug 2020 04:34:05
User entered 'None (0)'	System	09 Aug 2020 04:34:05

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T00:33:44', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '6004e5c1-089f-46f5-a1ae-6ee6f7c2da06'	System	09 Aug 2020 04:34:05
User entered 'None (0)'	System	09 Aug 2020 04:34:05

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

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)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T00:33:54', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '6004e5c1-089f-46f5-a1ae-6ee6f7c2da06'	System	09 Aug 2020 04:34:05
User entered 'No (N)'	System	09 Aug 2020 04:34:05

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T00:33:58', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '6004e5c1-089f-46f5-a1ae-6ee6f7c2da06' User entered '09 Aug 2020 00:33'	System	09 Aug 2020 04:34:05
	System	09 Aug 2020 04:34:05

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered 'Day 3'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T22:22:08', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '38e4ab3d-6f23-4f9f-b0db-c7a61bb5df29'	System	10 Aug 2020 02:23:06
User entered 'None (0)'	System	10 Aug 2020 02:23:06

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T22:22:22', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '38e4ab3d-6f23-4f9f-b0db-c7a61bb5df29'	System	10 Aug 2020 02:23:06
User entered 'No interference with activity (1)'	System	10 Aug 2020 02:23:06

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T22:22:25', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '38e4ab3d-6f23-4f9f-b0db-c7a61bb5df29'	System	10 Aug 2020 02:23:06
User entered 'None (0)'	System	10 Aug 2020 02:23:06

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T22:22:28', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '38e4ab3d-6f23-4f9f-b0db-c7a61bb5df29'	System	10 Aug 2020 02:23:06
User entered 'None (0)'	System	10 Aug 2020 02:23:06

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T22:22:30', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '38e4ab3d-6f23-4f9f-b0db-c7a61bb5df29'	System	10 Aug 2020 02:23:06
User entered 'None (0)'	System	10 Aug 2020 02:23:06

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T22:22:32', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '38e4ab3d-6f23-4f9f-b0db-c7a61bb5df29'	System	10 Aug 2020 02:23:06
User entered 'None (0)'	System	10 Aug 2020 02:23:06

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

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)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T22:22:58', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '38e4ab3d-6f23-4f9f-b0db-c7a61bb5df29'	System	10 Aug 2020 02:23:06
User entered 'No (N)'	System	10 Aug 2020 02:23:06

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T22:23:02', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '38e4ab3d-6f23-4f9f-b0db-c7a61bb5df29' User entered '09 Aug 2020 22:23'	System	10 Aug 2020 02:23:06
	System	10 Aug 2020 02:23:06

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered 'Day 4'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-10T13:05:34', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'eec6c038-397e-42c5-8cab-01abf315b5e7'	System	10 Aug 2020 17:08:48
User entered 'None (0)'	System	10 Aug 2020 17:08:48

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-10T13:05:38', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'eec6c038-397e-42c5-8cab-01abf315b5e7'	System	10 Aug 2020 17:08:48
User entered 'None (0)'	System	10 Aug 2020 17:08:48

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-10T13:08:26', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'eec6c038-397e-42c5-8cab-01abf315b5e7'	System	10 Aug 2020 17:08:48
User entered 'None (0)'	System	10 Aug 2020 17:08:48

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-10T13:08:29', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'eec6c038-397e-42c5-8cab-01abf315b5e7'	System	10 Aug 2020 17:08:48
User entered 'None (0)'	System	10 Aug 2020 17:08:48

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-10T13:08:32', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'eec6c038-397e-42c5-8cab-01abf315b5e7'	System	10 Aug 2020 17:08:48
User entered 'None (0)'	System	10 Aug 2020 17:08:48

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-10T13:08:36', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'eec6c038-397e-42c5-8cab-01abf315b5e7'	System	10 Aug 2020 17:08:48
User entered 'None (0)'	System	10 Aug 2020 17:08:48

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

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)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-10T13:08:39', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'eec6c038-397e-42c5-8cab-01abf315b5e7'	System	10 Aug 2020 17:08:48
User entered 'No (N)'	System	10 Aug 2020 17:08:48

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-10T13:08:45', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'eec6c038-397e-42c5-8cab-01abf315b5e7'	System	10 Aug 2020 17:08:48
User entered '10 Aug 2020 13:08'	System	10 Aug 2020 17:08:48

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered 'Day 5'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-11T23:27:52', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e7dd3c05-0993-496f-a01a-021fa8fafc3b'	System	12 Aug 2020 03:28:31
User entered 'No interference with activity (1)'	System	12 Aug 2020 03:28:31

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-11T23:27:57', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e7dd3c05-0993-496f-a01a-021fa8fafc3b'	System	12 Aug 2020 03:28:31
User entered 'No interference with activity (1)'	System	12 Aug 2020 03:28:31

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-11T23:28:04', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e7dd3c05-0993-496f-a01a-021fa8fafc3b'	System	12 Aug 2020 03:28:31
User entered 'No interference with activity (1)'	System	12 Aug 2020 03:28:31

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-11T23:28:08', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e7dd3c05-0993-496f-a01a-021fa8fafc3b'	System	12 Aug 2020 03:28:31
User entered 'None (0)'	System	12 Aug 2020 03:28:31

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-11T23:28:21', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e7dd3c05-0993-496f-a01a-021fa8fafc3b'	System	12 Aug 2020 03:28:31
User entered 'None (0)'	System	12 Aug 2020 03:28:31

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-11T23:28:24', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e7dd3c05-0993-496f-a01a-021fa8fafc3b'	System	12 Aug 2020 03:28:31
User entered 'None (0)'	System	12 Aug 2020 03:28:31

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

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)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-11T23:28:27', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e7dd3c05-0993-496f-a01a-021fa8fafc3b'	System	12 Aug 2020 03:28:31
User entered 'No (N)'	System	12 Aug 2020 03:28:31

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-11T23:28:30', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e7dd3c05-0993-496f-a01a-021fa8fafc3b'	System	12 Aug 2020 03:28:31
User entered '11 Aug 2020 23:28'	System	12 Aug 2020 03:28:31

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered 'Day 6'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-12T17:08:47', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9ef149ad-4ae9-4759-bd37-2a79a883eafb'	System	12 Aug 2020 21:09:45
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	12 Aug 2020 21:09:45

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-12T17:08:54', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9ef149ad-4ae9-4759-bd37-2a79a883eafb'	System	12 Aug 2020 21:09:45
User entered 'Some interference with activity (2)'	System	12 Aug 2020 21:09:45

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-12T17:09:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9ef149ad-4ae9-4759-bd37-2a79a883eafb'	System	12 Aug 2020 21:09:45
User entered 'No interference with activity (1)'	System	12 Aug 2020 21:09:45

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-12T17:09:08', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9ef149ad-4ae9-4759-bd37-2a79a883eafb'	System	12 Aug 2020 21:09:45
User entered 'No interference with activity (1)'	System	12 Aug 2020 21:09:45

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-12T17:09:10', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9ef149ad-4ae9-4759-bd37-2a79a883eafb'	System	12 Aug 2020 21:09:45
User entered 'None (0)'	System	12 Aug 2020 21:09:45

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-12T17:09:13', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9ef149ad-4ae9-4759-bd37-2a79a883eafb'	System	12 Aug 2020 21:09:45
User entered 'None (0)'	System	12 Aug 2020 21:09:45

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

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)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-12T17:09:17', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9ef149ad-4ae9-4759-bd37-2a79a883eafb'	System	12 Aug 2020 21:09:45
User entered 'No (N)'	System	12 Aug 2020 21:09:45

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-12T17:09:42', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9ef149ad-4ae9-4759-bd37-2a79a883eafb'	System	12 Aug 2020 21:09:45
User entered '12 Aug 2020 17:09'	System	12 Aug 2020 21:09:45

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered 'Day 7'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-13T14:45:23', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bd9a1a27-3b17-424e-aff0-18d3e10e05b6'	System	13 Aug 2020 18:45:57
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	13 Aug 2020 18:45:57

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-13T14:45:31', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bd9a1a27-3b17-424e-aff0-18d3e10e05b6'	System	13 Aug 2020 18:45:57
User entered 'Some interference with activity (2)'	System	13 Aug 2020 18:45:57

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-13T14:45:35', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bd9a1a27-3b17-424e-aff0-18d3e10e05b6'	System	13 Aug 2020 18:45:57
User entered 'No interference with activity (1)'	System	13 Aug 2020 18:45:57

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-13T14:45:44', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bd9a1a27-3b17-424e-aff0-18d3e10e05b6'	System	13 Aug 2020 18:45:57
User entered 'None (0)'	System	13 Aug 2020 18:45:57

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-13T14:45:46', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bd9a1a27-3b17-424e-aff0-18d3e10e05b6'	System	13 Aug 2020 18:45:57
User entered 'None (0)'	System	13 Aug 2020 18:45:57

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-13T14:45:48', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bd9a1a27-3b17-424e-aff0-18d3e10e05b6'	System	13 Aug 2020 18:45:57
User entered 'None (0)'	System	13 Aug 2020 18:45:57

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

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)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-13T14:45:51', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bd9a1a27-3b17-424e-aff0-18d3e10e05b6'	System	13 Aug 2020 18:45:57
User entered 'No (N)'	System	13 Aug 2020 18:45:57

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-13T14:45:53', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bd9a1a27-3b17-424e-aff0-18d3e10e05b6'	System	13 Aug 2020 18:45:57
User entered '13 Aug 2020 14:45'	System	13 Aug 2020 18:45:57

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 20:19:38

US3202057

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	12 Aug 2020 21:09:45
User entered 'Day 8'	System	12 Aug 2020 21:09:45

US3202057

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:05:41

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-14T17:04:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ec946f4a-793b-46b2-88ef-f93eb0a149b5'	System	14 Aug 2020 21:04:26
User entered 'No interference with activity (1)'	System	14 Aug 2020 21:04:26

US3202057

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-14T17:04:20', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ec946f4a-793b-46b2-88ef-f93eb0a149b5'	System	14 Aug 2020 21:04:26
User entered '14 Aug 2020 17:04'	System	14 Aug 2020 21:04:26

US3202057

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 21:09:45

US3202057

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 21:09:45

US3202057

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	13 Aug 2020 18:45:57
User entered 'Day 9'	System	13 Aug 2020 18:45:57

US3202057

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:05:41

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-15T23:22:13', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '01237f5e-29d2-416f-84e0-578dbe296350'	System	16 Aug 2020 03:22:52
User entered 'None (0)'	System	16 Aug 2020 03:22:52

US3202057

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-15T23:22:50', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '01237f5e-29d2-416f-84e0-578dbe296350'	System	16 Aug 2020 03:22:52
User entered '15 Aug 2020 23:22'	System	16 Aug 2020 03:22:52

US3202057

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 18:45:57

US3202057

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 18:45:57

US3202057

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	12 Aug 2020 21:09:45
User entered 'Day 8'	System	12 Aug 2020 21:09:45

US3202057

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:05:41

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-14T17:04:27', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f42d0791-6d7c-453a-9784-2b035bfd5085'	System	14 Aug 2020 21:04:33
User entered 'No interference with activity (1)'	System	14 Aug 2020 21:04:33

US3202057

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-14T17:04:29', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f42d0791-6d7c-453a-9784-2b035bfd5085'	System	14 Aug 2020 21:04:33
User entered '14 Aug 2020 17:04'	System	14 Aug 2020 21:04:33

US3202057

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 21:09:45

US3202057

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 21:09:45

US3202057

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	13 Aug 2020 18:45:57
User entered 'Day 9'	System	13 Aug 2020 18:45:57

US3202057

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:05:41

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-15T23:22:54', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '47482077-500e-4204-8c88-88e17250bc5c'	System	16 Aug 2020 03:22:58
User entered 'None (0)'	System	16 Aug 2020 03:22:58

US3202057

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-15T23:22:56', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '47482077-500e-4204-8c88-88e17250bc5c'	System	16 Aug 2020 03:22:58
User entered '15 Aug 2020 23:22'	System	16 Aug 2020 03:22:58

US3202057

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 18:45:57

US3202057

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 18:45:57

US3202057

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	12 Aug 2020 21:09:45
User entered 'Day 8'	System	12 Aug 2020 21:09:45

US3202057

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 11 Aug 2021 22:05:41

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-14T17:04:34', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '3b8d94a6-35f7-412e-80ea-a3cb071809ca'	System	14 Aug 2020 21:04:39
User entered 'No interference with activity (1)'	System	14 Aug 2020 21:04:39

US3202057

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-14T17:04:36', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '3b8d94a6-35f7-412e-80ea-a3cb071809ca'	System	14 Aug 2020 21:04:39
User entered '14 Aug 2020 17:04'	System	14 Aug 2020 21:04:39

US3202057

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 21:09:45

US3202057

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 21:09:45

US3202057

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	13 Aug 2020 18:45:57
User entered 'Day 9'	System	13 Aug 2020 18:45:57

US3202057

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 11 Aug 2021 22:05:41

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-15T23:23:03', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1c0801e2-9273-4699-8f65-6f30a1f3386d'	System	16 Aug 2020 03:23:10
User entered 'None (0)'	System	16 Aug 2020 03:23:10

US3202057

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-15T23:23:05', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1c0801e2-9273-4699-8f65-6f30a1f3386d'	System	16 Aug 2020 03:23:10
User entered '15 Aug 2020 23:23'	System	16 Aug 2020 03:23:10

US3202057

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 18:45:57

US3202057

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 18:45:57

US3202057

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	12 Aug 2020 21:09:45
User entered 'Day 8'	System	12 Aug 2020 21:09:45

US3202057

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:05:41

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)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-14T17:04:41', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '8131d1d2-700e-496f-95d0-1a519954a3d1'	System	14 Aug 2020 21:04:50
User entered 'No (N)'	System	14 Aug 2020 21:04:50

US3202057

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-14T17:04:46', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '8131d1d2-700e-496f-95d0-1a519954a3d1'	System	14 Aug 2020 21:04:50
User entered '14 Aug 2020 17:04'	System	14 Aug 2020 21:04:50

US3202057

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 21:09:45

US3202057

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 21:09:45

US3202057

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	13 Aug 2020 18:44:48
User entered 'Day 9'	System	13 Aug 2020 18:44:48

US3202057

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:05:41

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)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-15T23:23:09', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'a0bf416a-b5ee-4566-b8a9-c4952ad7137b'	System	16 Aug 2020 03:23:16
User entered 'No (N)'	System	16 Aug 2020 03:23:16

US3202057

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-15T23:23:11', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'a0bf416a-b5ee-4566-b8a9-c4952ad7137b'	System	16 Aug 2020 03:23:16
User entered '15 Aug 2020 23:23'	System	16 Aug 2020 03:23:16

US3202057

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 18:44:48

US3202057

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 18:44:48

US3202057

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	19 Aug 2020 14:12:17

US3202057

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	25 Aug 2020 11:09:10
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'yes, this was secondary to business hours' (Site from System).	Lilian Nukuna (b) (4) (b) (4)	19 Aug 2020 14:12:56
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	19 Aug 2020 14:12:17
User entered '19 Aug 2020'	Lilian Nukuna (b) (4) (b) (4)	19 Aug 2020 14:12:17

US3202057

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4)	19 Aug 2020 14:12:17

US3202057

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered empty.	(b) (4) Lilian Nukuna (b) (4)	19 Aug 2020 14:12:17
	(b) (4)	

US3202057

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	19 Aug 2020 14:13:07

US3202057

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered '1'	System	19 Aug 2020 14:13:07

US3202057

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:25:35

US3202057

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:11:18
User entered '20 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 16:26:36
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'OOW as noted in EDC' (Site from System).	(b) (4), (b) (6)	16 Sep 2020 16:26:01
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	16 Sep 2020 16:25:35
User entered '27 Aug 2020'	(b) (4), (b) (6)	16 Sep 2020 16:25:35

US3202057

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:25:35

US3202057

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:25:35

US3202057

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 18:22:45

US3202057

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered '1'	System	03 Sep 2020 18:22:45

US3202057

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:26:53

US3202057

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:35:56
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'OOW as noted in source' (Site from System).	(b) (4), (b) (6)	16 Sep 2020 16:27:01
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	16 Sep 2020 16:26:53
User entered '27 Aug 2020'	(b) (4), (b) (6)	16 Sep 2020 16:26:53

US3202057

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:26:53

US3202057

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:26:53

US3202057

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 18:22:51

US3202057

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered '1'	System	03 Sep 2020 18:22:51

US3202057

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 18:23:02

US3202057

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	06 Sep 2020 10:32:09
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	03 Sep 2020 18:23:02
User entered '3 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	03 Sep 2020 18:23:02

US3202057

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User entered 'Clinic (Clinic)'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 18:23:02

US3202057

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered 'VISIT2'	System	03 Sep 2020 18:23:02

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	16 Sep 2020 16:45:50

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:45:50

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:45:50

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	16 Sep 2020 16:46:42
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	16 Sep 2020 16:46:42
User entered '13:37' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 16:46:42
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 16:45:50
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 16:45:50

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered '03 Sep 2020 13:37'	System	16 Sep 2020 16:46:42
User entered empty.	System	16 Sep 2020 16:45:50

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	16 Sep 2020 16:46:42
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	16 Sep 2020 16:46:42
User entered '37.1' C reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 16:46:42
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 16:45:50
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 16:45:50

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:46:42
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 16:45:50

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:45:50

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	16 Sep 2020 16:46:42
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	16 Sep 2020 16:46:42
User entered '76' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 16:46:42
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 16:45:50
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 16:45:50

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered 'bpm'	System	16 Sep 2020 16:46:42
User entered empty.	System	16 Sep 2020 16:45:50

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	16 Sep 2020 16:46:42
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	16 Sep 2020 16:46:42
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 16:46:42
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 16:45:50
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 16:45:50

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered 'breaths/min'	System	16 Sep 2020 16:46:42
User entered empty.	System	16 Sep 2020 16:45:50

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	16 Sep 2020 16:46:42
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	16 Sep 2020 16:46:42
User entered '100' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 16:46:42
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 16:45:50
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 16:45:50

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered 'mmHg'	System	16 Sep 2020 16:46:42
User entered empty.	System	16 Sep 2020 16:45:50

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User closed query 'Per CDM: Response is noted; however, please advise if out of range value is either NCS or CS. If CS, please add the event to the adverse event form' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:12:11
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	16 Oct 2020 15:12:10
Query 'Per CDM: Response is noted; however, please advise if out of range value is either NCS or CS. If CS, please add the event to the adverse event form' answered with 'NCS' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	26 Sep 2020 17:01:40
User opened query 'Per CDM: Response is noted; however, please advise if out of range value is either NCS or CS. If CS, please add the event to the adverse event form' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 14:44:35
Comment added 'NCS*'. Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'fixed' (Site from System).	zackery harmon (b) (4) (b) (4) zackery harmon (b) (4) (b) (4)	18 Sep 2020 12:24:56 18 Sep 2020 12:24:44
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:47:46
User closed query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 16:46:42
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	16 Sep 2020 16:46:42
User entered '58' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 16:46:42
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 16:45:50

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 16:45:50

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered 'mmHg'	System	16 Sep 2020 16:46:42
User entered empty.	System	16 Sep 2020 16:45:50

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	16 Sep 2020 16:45:50

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:45:50

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:45:50

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User closed query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	(b) (4) System	16 Sep 2020 16:48:16
User entered '15:06' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 16:48:16
User opened query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	System	16 Sep 2020 16:47:40
User closed query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 16:47:40
Query 'Data is required. Please provide.' answered by System data change (Site from System).		16 Sep 2020 16:47:40
User entered '13:06' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 16:47:40
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 16:45:50
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 16:45:50

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered '03 Sep 2020 15:06'	System	16 Sep 2020 16:48:16
User entered '03 Sep 2020 13:06'	System	16 Sep 2020 16:47:40
User entered empty.	System	16 Sep 2020 16:45:50

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	16 Sep 2020 16:47:40
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	16 Sep 2020 16:47:40
User entered '36.9' C reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 16:47:40
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 16:45:50
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 16:45:50

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:47:40
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 16:45:50

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:45:50

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	16 Sep 2020 16:47:40
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	16 Sep 2020 16:47:40
User entered '67' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 16:47:40
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 16:45:50
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 16:45:50

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered 'bpm'	System	16 Sep 2020 16:47:40
User entered empty.	System	16 Sep 2020 16:45:50

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	16 Sep 2020 16:47:40
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	16 Sep 2020 16:47:40
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 16:47:40
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 16:45:50
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 16:45:50

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered 'breaths/min'	System	16 Sep 2020 16:47:40
User entered empty.	System	16 Sep 2020 16:45:50

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	16 Sep 2020 16:47:40
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	16 Sep 2020 16:47:40
User entered '118' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 16:47:40
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 16:45:50
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 16:45:50

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered 'mmHg'	System	16 Sep 2020 16:47:40
User entered empty.	System	16 Sep 2020 16:45:50

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	16 Sep 2020 16:47:40
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	16 Sep 2020 16:47:40
User entered '76' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 16:47:40
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 16:45:50
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 16:45:50

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered 'mmHg'	System	16 Sep 2020 16:47:40
User entered empty.	System	16 Sep 2020 16:45:50

US3202057

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	04 Sep 2020 18:15:44

US3202057

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	04 Sep 2020 18:15:44

US3202057

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:48:55

US3202057

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:48:55

US3202057

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:48:55

US3202057

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:48:55

US3202057

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:48:55

US3202057

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:48:55

US3202057

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User entered '13:20'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:48:55

US3202057

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered '03 Sep 2020 13:20'	System	16 Sep 2020 16:48:55

US3202057

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 18:23:24

US3202057

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 18:23:24

US3202057

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

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)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 18:23:24
	(b) (4)	

US3202057

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 18:23:24

US3202057

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '3 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 18:23:24

US3202057

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '14:15'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 18:23:24

US3202057

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered '3 Sep 2020 14:15'	System	03 Sep 2020 18:23:24

US3202057

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Left Arm (LEFT ARM)'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 18:23:24

US3202057

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered 'ONCE'	System	03 Sep 2020 18:23:24

US3202057

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 18:23:24

US3202057

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	04 Sep 2020 18:15:37

US3202057

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 03SEP2020 is recorded under Visit2 Day29 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). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 03SEP2020 is recorded under Visit2 Day29 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 'DCF for correct visit submitted to PPD Central lab on date of collection--EDC visit name is correct. Kit supply issues necessitated use of Unscheduled kit for this visit.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:02:16
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 03SEP2020 is recorded under Visit2 Day29 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 'DCF for correct visit submitted to PPD Central lab on date of collection--EDC visit name is correct. Kit supply issues necessitated use of Unscheduled kit for this visit.' (Site from DM).	Erica Osmundsen (b) (4)	19 Oct 2020 14:52:26
User entered '3 Sep 2020'	(b) (4), (b) (6)	19 Oct 2020 05:30:51
	Tiffany Jewell (b) (4)	04 Sep 2020 18:15:37
	(b) (4)	

US3202057

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User entered '13:51'	(b) (4) Tiffany Jewell (b) (4)	04 Sep 2020 18:15:37

US3202057

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered '3 Sep 2020 13:51'	System	04 Sep 2020 18:15:37

US3202057

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:05:41

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 03SEP2020 is recorded under Visit 2 Day 29 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)	20 Nov 2020 10:36:24
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 03SEP2020 is recorded under Visit 2 Day 29 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 'DCF sent; PPD to correct' (Site from DM).	Teresa Deese (b) (4)	05 Nov 2020 20:35:45
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 03SEP2020 is recorded under Visit 2 Day 29 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)	02 Nov 2020 04:49:00
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 03SEP2020 is recorded under Visit2 Day29 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)	24 Oct 2020 21:31:05
Query 'Per GCL Lab Reconciliation: Nasopharyngeal zackery harmon Swab 1: Sample dated 03SEP2020 is recorded under Visit2 Day29 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 'DCF reported, data in edc is accurate' (Site from DM).	(b) (4) (b) (4)	21 Oct 2020 19:00:38

US3202057

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:05:41

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 03SEP2020 is recorded under Visit2 Day29 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). User entered '3 Sep 2020'	(b) (4), (b) (6)	20 Oct 2020 04:23:32
	Tiffany Jewell (b) (4) (b) (4)	04 Sep 2020 18:14:33

US3202057

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:05:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tiffany Jewell (b) (4) (b) (4)	04 Sep 2020 18:14:33

US3202057

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:05:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	04 Sep 2020 18:14:33

US3202057

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:05:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '13:49'	(b) (4) Tiffany Jewell (b) (4)	04 Sep 2020 18:14:33

US3202057

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:05:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered '3 Sep 2020 13:49'	System	04 Sep 2020 18:14:33

US3202057

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:05:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tiffany Jewell (b) (4) (b) (4)	04 Sep 2020 18:14:33

US3202057

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:05:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	04 Sep 2020 18:14:33

US3202057

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:05:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	04 Sep 2020 18:14:33

US3202057

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:05:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered empty.	System	04 Sep 2020 18:14:33

US3202057

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 18:37:37

US3202057

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered '1'	System	03 Sep 2020 18:37:37

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	03 Sep 2020 18:23:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T14:43:47', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '32e475e9-cb0a-4e1a-894a-c4b00a088a33'	System	03 Sep 2020 18:44:13
User entered 'Yes (Y)'	System	03 Sep 2020 18:44:13

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T14:43:52', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '32e475e9-cb0a-4e1a-894a-c4b00a088a33'	System	03 Sep 2020 18:44:13
User entered '98.5'	System	03 Sep 2020 18:44:13

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T14:44:03', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '32e475e9-cb0a-4e1a-894a-c4b00a088a33'	System	03 Sep 2020 18:44:13
User entered 'No (N)'	System	03 Sep 2020 18:44:13

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T14:44:05', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '32e475e9-cb0a-4e1a-894a-c4b00a088a33'	System	03 Sep 2020 18:44:13
User entered '03 Sep 2020 14:44'	System	03 Sep 2020 18:44:13

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '03 Sep 2020 14:35'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '03 Sep 2020 17:05'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	03 Sep 2020 18:23:24
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T18:42:38', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'd013a6cb-0421-4247-9442-c5142637433d'	System	03 Sep 2020 22:43:04
User entered 'Yes (Y)'	System	03 Sep 2020 22:43:04

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T18:42:50', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'd013a6cb-0421-4247-9442-c5142637433d'	System	03 Sep 2020 22:43:04
User entered '98.4'	System	03 Sep 2020 22:43:04

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T18:42:54', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'd013a6cb-0421-4247-9442-c5142637433d'	System	03 Sep 2020 22:43:04
User entered 'No (N)'	System	03 Sep 2020 22:43:04

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T18:42:59', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'd013a6cb-0421-4247-9442-c5142637433d'	System	03 Sep 2020 22:43:04
User entered '03 Sep 2020 18:42'	System	03 Sep 2020 22:43:04

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '03 Sep 2020 18:00'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	03 Sep 2020 18:23:24
User entered 'Day 2'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-04T18:07:46', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e7ed9dd4-52e6-4fcf-bf11-51bd1e4e043f'	System	04 Sep 2020 22:10:24
User entered 'Yes (Y)'	System	04 Sep 2020 22:10:24

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-04T18:08:32', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e7ed9dd4-52e6-4fcf-bf11-51bd1e4e043f' User entered '98.4'	System	04 Sep 2020 22:10:24
	System	04 Sep 2020 22:10:24

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:05:41

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-04T18:09:59', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e7ed9dd4-52e6-4fcf-bf11-51bd1e4e043f' User entered 'Yes (Y)'	System	04 Sep 2020 22:10:24
	System	04 Sep 2020 22:10:24

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:05:41

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'meds/reason unknown- subject at site for illness visit on 13 Sep with symptoms that started 09 Sep' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 11:02:25
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	16 Sep 2020 16:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-04T18:10:13', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e7ed9dd4-52e6-4fcf-bf11-51bd1e4e043f'	System	04 Sep 2020 22:10:24
User entered '1'	System	04 Sep 2020 22:10:24

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:05:41

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-04T18:10:13', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e7ed9dd4-52e6-4fcf-bf11-51bd1e4e043f' User entered '0'	System	04 Sep 2020 22:10:24
	System	04 Sep 2020 22:10:24

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-04T18:10:21', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e7ed9dd4-52e6-4fcf-bf11-51bd1e4e043f' User entered '04 Sep 2020 18:10'	System	04 Sep 2020 22:10:24
	System	04 Sep 2020 22:10:24

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	03 Sep 2020 18:23:24
User entered 'Day 3'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:05:41

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:05:41

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:05:41

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	03 Sep 2020 18:23:24
User entered 'Day 4'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-06T22:45:44', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ef64e7bd-f448-4e17-ace3-20ab116ecf92'	System	07 Sep 2020 02:46:00
User entered 'Yes (Y)'	System	07 Sep 2020 02:46:00

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-06T22:45:50', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ef64e7bd-f448-4e17-ace3-20ab116ecf92'	System	07 Sep 2020 02:46:00
User entered '98.1'	System	07 Sep 2020 02:46:00

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:05:41

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-06T22:45:53', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ef64e7bd-f448-4e17-ace3-20ab116ecf92'	System	07 Sep 2020 02:46:00
User entered 'No (N)'	System	07 Sep 2020 02:46:00

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-06T22:45:56', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ef64e7bd-f448-4e17-ace3-20ab116ecf92'	System	07 Sep 2020 02:46:00
User entered '06 Sep 2020 22:45'	System	07 Sep 2020 02:46:00

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	03 Sep 2020 18:23:24
User entered 'Day 5'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-07T13:30:14', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'c10b23c9-3482-46db-8a74-59bdc17feb57'	System	07 Sep 2020 17:31:05
User entered 'Yes (Y)'	System	07 Sep 2020 17:31:05

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-07T13:30:39', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'c10b23c9-3482-46db-8a74-59bdc17feb57'	System	07 Sep 2020 17:31:05
User entered '98.4'	System	07 Sep 2020 17:31:05

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:05:41

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-07T13:30:43', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'c10b23c9-3482-46db-8a74-59bdc17feb57'	System	07 Sep 2020 17:31:05
User entered 'No (N)'	System	07 Sep 2020 17:31:05

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-07T13:30:59', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'c10b23c9-3482-46db-8a74-59bdc17feb57'	System	07 Sep 2020 17:31:05
User entered '07 Sep 2020 13:30'	System	07 Sep 2020 17:31:05

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	03 Sep 2020 18:23:24
User entered 'Day 6'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-08T14:33:32', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ffc1a277-baf2-4dbd-bf34-f3afd0852103'	System	08 Sep 2020 18:33:54
User entered 'Yes (Y)'	System	08 Sep 2020 18:33:54

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-08T14:33:38', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ffc1a277-baf2-4dbd-bf34-f3afd0852103'	System	08 Sep 2020 18:33:54
User entered '99.0'	System	08 Sep 2020 18:33:54

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:05:41

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-08T14:33:47', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ffc1a277-baf2-4dbd-bf34-f3afd0852103'	System	08 Sep 2020 18:33:54
User entered 'No (N)'	System	08 Sep 2020 18:33:54

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-08T14:33:50', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ffc1a277-baf2-4dbd-bf34-f3afd0852103'	System	08 Sep 2020 18:33:54
User entered '08 Sep 2020 14:33'	System	08 Sep 2020 18:33:54

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	03 Sep 2020 18:23:24
User entered 'Day 7'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-09T19:45:17', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '7b9ec68d-f304-4051-a91e-3a3c2982c1d2'	System	09 Sep 2020 23:46:10
User entered 'Yes (Y)'	System	09 Sep 2020 23:46:10

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-09T19:45:35', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '7b9ec68d-f304-4051-a91e-3a3c2982c1d2'	System	09 Sep 2020 23:46:10
User entered '100.5'	System	09 Sep 2020 23:46:10

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:41

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-09T19:45:44', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '7b9ec68d-f304-4051-a91e-3a3c2982c1d2'	System	09 Sep 2020 23:46:10
User entered 'Yes (Y)'	System	09 Sep 2020 23:46:10

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:41

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'noted as AE' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 10:59:23
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'noted as AE' (Site from System).	(b) (4), (b) (6)	16 Sep 2020 16:35:06
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	09 Sep 2020 23:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-09T19:45:49', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '7b9ec68d-f304-4051-a91e-3a3c2982c1d2'	System	09 Sep 2020 23:46:10
User entered '1'	System	09 Sep 2020 23:46:10

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:41

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-09T19:45:49', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '7b9ec68d-f304-4051-a91e-3a3c2982c1d2'	System	09 Sep 2020 23:46:10
User entered '0'	System	09 Sep 2020 23:46:10

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-09T19:46:02', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '7b9ec68d-f304-4051-a91e-3a3c2982c1d2'	System	09 Sep 2020 23:46:10
User entered '09 Sep 2020 19:46'	System	09 Sep 2020 23:46:10

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	09 Sep 2020 23:46:10
User entered 'Day 8'	System	09 Sep 2020 23:46:10

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:05:41

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:05:41

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:05:41

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 23:46:10

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 23:46:10

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	09 Sep 2020 23:46:10
User entered 'Day 9'	System	09 Sep 2020 23:46:10

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-11T13:49:01', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '23749d8b-6dee-42db-a1ea-5d0833e33bca'	System	11 Sep 2020 17:49:39
User entered 'Yes (Y)'	System	11 Sep 2020 17:49:39

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-11T13:49:09', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '23749d8b-6dee-42db-a1ea-5d0833e33bca'	System	11 Sep 2020 17:49:39
User entered '98.1'	System	11 Sep 2020 17:49:39

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:05:41

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-11T13:49:13', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '23749d8b-6dee-42db-a1ea-5d0833e33bca'	System	11 Sep 2020 17:49:39
User entered 'Yes (Y)'	System	11 Sep 2020 17:49:39

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:05:41

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'noted as AE' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 10:59:42
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	16 Sep 2020 16:35:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-11T13:49:19', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '23749d8b-6dee-42db-a1ea-5d0833e33bca'	System	11 Sep 2020 17:49:39
User entered '1'	System	11 Sep 2020 17:49:39

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:05:41

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-11T13:49:19', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '23749d8b-6dee-42db-a1ea-5d0833e33bca'	System	11 Sep 2020 17:49:39
User entered '0'	System	11 Sep 2020 17:49:39

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-11T13:49:33', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '23749d8b-6dee-42db-a1ea-5d0833e33bca'	System	11 Sep 2020 17:49:39
User entered '11 Sep 2020 13:49'	System	11 Sep 2020 17:49:39

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 23:46:10

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 23:46:10

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	11 Sep 2020 17:49:39
User entered 'Day 10'	System	11 Sep 2020 17:49:39

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-12T20:30:14', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '55124b5a-1cf1-4e44-be56-a8fb35cddb8b'	System	13 Sep 2020 00:30:57
User entered 'Yes (Y)'	System	13 Sep 2020 00:30:57

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-12T20:30:43', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '55124b5a-1cf1-4e44-be56-a8fb35cddb8b'	System	13 Sep 2020 00:30:57
User entered '96.8'	System	13 Sep 2020 00:30:57

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 11 Aug 2021 22:05:41

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-12T20:30:48', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '55124b5a-1cf1-4e44-be56-a8fb35cddb8b'	System	13 Sep 2020 00:30:57
User entered 'Yes (Y)'	System	13 Sep 2020 00:30:57

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 11 Aug 2021 22:05:41

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Pt was contacted and brought in for an illness visit' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 14:49:07
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	zackery harmon (b) (4)	24 Sep 2020 13:18:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-12T20:30:51', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '55124b5a-1cf1-4e44-be56-a8fb35cddb8b'	(b) (4)	
User entered '1'	System	13 Sep 2020 00:30:57
	System	13 Sep 2020 00:30:57
	System	13 Sep 2020 00:30:57

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 11 Aug 2021 22:05:41

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-12T20:30:51', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '55124b5a-1cf1-4e44-be56-a8fb35cddb8b'	System	13 Sep 2020 00:30:57
User entered '0'	System	13 Sep 2020 00:30:57

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-12T20:30:53', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '55124b5a-1cf1-4e44-be56-a8fb35cddb8b'	System	13 Sep 2020 00:30:57
User entered '12 Sep 2020 20:30'	System	13 Sep 2020 00:30:57

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 17:49:39

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 17:49:39

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	11 Sep 2020 17:49:39
User entered 'Day 11'	System	11 Sep 2020 17:49:39

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-13T18:58:08', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '4eb16aee-2451-411d-b33b-0590b31707c2'	System	13 Sep 2020 22:58:26
User entered 'Yes (Y)'	System	13 Sep 2020 22:58:26

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-13T18:58:14', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '4eb16aee-2451-411d-b33b-0590b31707c2'	System	13 Sep 2020 22:58:26
User entered '98.1'	System	13 Sep 2020 22:58:26

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 11 Aug 2021 22:05:41

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-13T18:58:18', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '4eb16aee-2451-411d-b33b-0590b31707c2'	System	13 Sep 2020 22:58:26
User entered 'No (N)'	System	13 Sep 2020 22:58:26

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-13T18:58:21', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '4eb16aee-2451-411d-b33b-0590b31707c2'	System	13 Sep 2020 22:58:26
User entered '13 Sep 2020 18:58'	System	13 Sep 2020 22:58:26

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 17:49:39

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 17:49:39

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	03 Sep 2020 18:23:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T14:41:18', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'de184afe-4cfd-4459-96a2-6532f3aaf056'	System	03 Sep 2020 18:41:48
User entered 'None (1)'	System	03 Sep 2020 18:41:48

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T14:41:21', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'de184afe-4cfd-4459-96a2-6532f3aaf056'	System	03 Sep 2020 18:41:48
User entered 'No (N)'	System	03 Sep 2020 18:41:48

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T14:41:30', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'de184afe-4cf4-4459-96a2-6532f3aaf056'	System	03 Sep 2020 18:41:48
User entered 'No (N)'	System	03 Sep 2020 18:41:48

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T14:41:38', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'de184afe-4cfd-4459-96a2-6532f3aaf056'	System	03 Sep 2020 18:41:48
User entered 'None (1)'	System	03 Sep 2020 18:41:48

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T14:41:44', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'de184afe-4cfd-4459-96a2-6532f3aaf056'	System	03 Sep 2020 18:41:48
User entered '03 Sep 2020 14:41'	System	03 Sep 2020 18:41:48

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '03 Sep 2020 14:35'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '03 Sep 2020 17:05'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	03 Sep 2020 18:23:24
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T18:43:09', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '81757af7-13a3-4b58-a2b7-62cdd3d582ce'	System	03 Sep 2020 22:44:12
User entered 'None (1)'	System	03 Sep 2020 22:44:12

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T18:43:12', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '81757af7-13a3-4b58-a2b7-62cdd3d582ce'	System	03 Sep 2020 22:44:12
User entered 'No (N)'	System	03 Sep 2020 22:44:12

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T18:43:32', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '81757af7-13a3-4b58-a2b7-62cdd3d582ce'	System	03 Sep 2020 22:44:12
User entered 'No (N)'	System	03 Sep 2020 22:44:12

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T18:43:43', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '81757af7-13a3-4b58-a2b7-62cdd3d582ce'	System	03 Sep 2020 22:44:12
User entered 'None (1)'	System	03 Sep 2020 22:44:12

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T18:44:07', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '81757af7-13a3-4b58-a2b7-62cdd3d582ce'	System	03 Sep 2020 22:44:12
User entered '03 Sep 2020 18:44'	System	03 Sep 2020 22:44:12

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '03 Sep 2020 18:00'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	03 Sep 2020 18:23:24
User entered 'Day 2'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:05:41

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-04T18:12:13', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '23a7d0aa-7a80-406c-a6b1-17b354ddd0a0'	System	04 Sep 2020 22:12:36
User entered 'None (1)'	System	04 Sep 2020 22:12:36

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:05:41

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-04T18:12:21', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '23a7d0aa-7a80-406c-a6b1-17b354ddd0a0'	System	04 Sep 2020 22:12:36
User entered 'No (N)'	System	04 Sep 2020 22:12:36

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:05:41

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-04T18:12:23', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '23a7d0aa-7a80-406c-a6b1-17b354ddd0a0'	System	04 Sep 2020 22:12:36
User entered 'No (N)'	System	04 Sep 2020 22:12:36

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:05:41

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-04T18:12:28', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '23a7d0aa-7a80-406c-a6b1-17b354ddd0a0'	System	04 Sep 2020 22:12:36
User entered 'None (1)'	System	04 Sep 2020 22:12:36

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-04T18:12:31', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '23a7d0aa-7a80-406c-a6b1-17b354ddd0a0'	System	04 Sep 2020 22:12:36
User entered '04 Sep 2020 18:12'	System	04 Sep 2020 22:12:36

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	03 Sep 2020 18:23:24
User entered 'Day 3'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:41

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:41

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:41

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:41

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:41

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:41

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	03 Sep 2020 18:23:24
User entered 'Day 4'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:05:41

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-06T22:46:04', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '19b3cd71-aca0-4a47-b86a-8f941defa0a0'	System	07 Sep 2020 02:47:11
User entered 'None (1)'	System	07 Sep 2020 02:47:11

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:05:41

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-06T22:46:33', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '19b3cd71-aca0-4a47-b86a-8f941defa0a0'	System	07 Sep 2020 02:47:11
User entered 'No (N)'	System	07 Sep 2020 02:47:11

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:05:41

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-06T22:46:36', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '19b3cd71-aca0-4a47-b86a-8f941defa0a0'	System	07 Sep 2020 02:47:11
User entered 'No (N)'	System	07 Sep 2020 02:47:11

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:05:41

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-06T22:47:02', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '19b3cd71-aca0-4a47-b86a-8f941defa0a0'	System	07 Sep 2020 02:47:11
User entered 'None (1)'	System	07 Sep 2020 02:47:11

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-06T22:47:08', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '19b3cd71-aca0-4a47-b86a-8f941defa0a0'	System	07 Sep 2020 02:47:11
User entered '06 Sep 2020 22:47'	System	07 Sep 2020 02:47:11

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	03 Sep 2020 18:23:24
User entered 'Day 5'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:41

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-07T13:34:47', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e98211d1-5d7a-4668-82ba-adf0fef154ee'	System	07 Sep 2020 17:36:05
User entered 'None (1)'	System	07 Sep 2020 17:36:05

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:41

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-07T13:34:50', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e98211d1-5d7a-4668-82ba-adf0fef154ee'	System	07 Sep 2020 17:36:05
User entered 'No (N)'	System	07 Sep 2020 17:36:05

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:41

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-07T13:35:20', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e98211d1-5d7a-4668-82ba-adf0fef154ee'	System	07 Sep 2020 17:36:05
User entered 'No (N)'	System	07 Sep 2020 17:36:05

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:41

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-07T13:35:50', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e98211d1-5d7a-4668-82ba-adf0fef154ee'	System	07 Sep 2020 17:36:05
User entered 'None (1)'	System	07 Sep 2020 17:36:05

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-07T13:36:01', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e98211d1-5d7a-4668-82ba-adf0fef154ee' User entered '07 Sep 2020 13:36'	System	07 Sep 2020 17:36:05
	System	07 Sep 2020 17:36:05

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	03 Sep 2020 18:23:24
User entered 'Day 6'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:05:41

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-08T14:34:16', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '19d61e82-05d0-4f92-9166-a7ed8bc4ce7f'	System	08 Sep 2020 18:35:20
User entered 'Does not interfere with activity (2)'	System	08 Sep 2020 18:35:20

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:05:41

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-08T14:34:34', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '19d61e82-05d0-4f92-9166-a7ed8bc4ce7f'	System	08 Sep 2020 18:35:20
User entered 'No (N)'	System	08 Sep 2020 18:35:20

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:05:41

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-08T14:34:41', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '19d61e82-05d0-4f92-9166-a7ed8bc4ce7f'	System	08 Sep 2020 18:35:20
User entered 'No (N)'	System	08 Sep 2020 18:35:20

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:05:41

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-08T14:34:55', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '19d61e82-05d0-4f92-9166-a7ed8bc4ce7f'	System	08 Sep 2020 18:35:20
User entered 'None (1)'	System	08 Sep 2020 18:35:20

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-08T14:35:18', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '19d61e82-05d0-4f92-9166-a7ed8bc4ce7f' User entered '08 Sep 2020 14:35'	System	08 Sep 2020 18:35:20
	System	08 Sep 2020 18:35:20

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	03 Sep 2020 18:23:24
User entered 'Day 7'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:05:41

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-09T19:46:36', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '555f4f7e-2bda-41fb-ac8a-f80c9553fd35'	System	09 Sep 2020 23:47:27
User entered 'None (1)'	System	09 Sep 2020 23:47:27

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:05:41

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-09T19:46:40', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '555f4f7e-2bda-41fb-ac8a-f80c9553fd35'	System	09 Sep 2020 23:47:27
User entered 'No (N)'	System	09 Sep 2020 23:47:27

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:05:41

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-09T19:47:18', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '555f4f7e-2bda-41fb-ac8a-f80c9553fd35'	System	09 Sep 2020 23:47:27
User entered 'No (N)'	System	09 Sep 2020 23:47:27

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:05:41

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-09T19:47:21', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '555f4f7e-2bda-41fb-ac8a-f80c9553fd35'	System	09 Sep 2020 23:47:27
User entered 'None (1)'	System	09 Sep 2020 23:47:27

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-09T19:47:24', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '555f4f7e-2bda-41fb-ac8a-f80c9553fd35' User entered '09 Sep 2020 19:47'	System	09 Sep 2020 23:47:27
	System	09 Sep 2020 23:47:27

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	03 Sep 2020 18:23:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T14:40:11', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '727278b3-c9aa-4029-aafd-883fbda824cb'	System	03 Sep 2020 18:41:10
User entered 'None (0)'	System	03 Sep 2020 18:41:10

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T14:40:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '727278b3-c9aa-4029-aafd-883fbda824cb'	System	03 Sep 2020 18:41:10
User entered 'None (0)'	System	03 Sep 2020 18:41:10

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T14:40:19', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '727278b3-c9aa-4029-aafd-883fbda824cb'	System	03 Sep 2020 18:41:10
User entered 'None (0)'	System	03 Sep 2020 18:41:10

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T14:40:37', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '727278b3-c9aa-4029-aafd-883fbda824cb'	System	03 Sep 2020 18:41:10
User entered 'None (0)'	System	03 Sep 2020 18:41:10

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T14:40:39', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '727278b3-c9aa-4029-aafd-883fbda824cb'	System	03 Sep 2020 18:41:10
User entered 'None (0)'	System	03 Sep 2020 18:41:10

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T14:40:46', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '727278b3-c9aa-4029-aafd-883fbda824cb'	System	03 Sep 2020 18:41:10
User entered 'None (0)'	System	03 Sep 2020 18:41:10

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

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)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T14:40:50', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '727278b3-c9aa-4029-aafd-883fbda824cb'	System	03 Sep 2020 18:41:10
User entered 'No (N)'	System	03 Sep 2020 18:41:10

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T14:41:07', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '727278b3-c9aa-4029-aafd-883fbda824cb'	System	03 Sep 2020 18:41:10
User entered '03 Sep 2020 14:41'	System	03 Sep 2020 18:41:10

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '03 Sep 2020 14:35'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '03 Sep 2020 17:05'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	03 Sep 2020 18:23:24
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T18:44:17', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1f75851e-d389-481d-aca7-ed6ba471b2d2'	System	03 Sep 2020 22:46:08
User entered 'No interference with activity (1)'	System	03 Sep 2020 22:46:08

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T18:44:30', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1f75851e-d389-481d-aca7-ed6ba471b2d2'	System	03 Sep 2020 22:46:08
User entered 'None (0)'	System	03 Sep 2020 22:46:08

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T18:44:33', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1f75851e-d389-481d-aca7-ed6ba471b2d2'	System	03 Sep 2020 22:46:08
User entered 'None (0)'	System	03 Sep 2020 22:46:08

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T18:44:38', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1f75851e-d389-481d-aca7-ed6ba471b2d2'	System	03 Sep 2020 22:46:08
User entered 'None (0)'	System	03 Sep 2020 22:46:08

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T18:44:58', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1f75851e-d389-481d-aca7-ed6ba471b2d2'	System	03 Sep 2020 22:46:08
User entered 'None (0)'	System	03 Sep 2020 22:46:08

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T18:45:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1f75851e-d389-481d-aca7-ed6ba471b2d2'	System	03 Sep 2020 22:46:08
User entered 'None (0)'	System	03 Sep 2020 22:46:08

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

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)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T18:45:09', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1f75851e-d389-481d-aca7-ed6ba471b2d2'	System	03 Sep 2020 22:46:08
User entered 'No (N)'	System	03 Sep 2020 22:46:08

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T18:46:04', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1f75851e-d389-481d-aca7-ed6ba471b2d2'	System	03 Sep 2020 22:46:08
User entered '03 Sep 2020 18:46'	System	03 Sep 2020 22:46:08

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '03 Sep 2020 18:00'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	03 Sep 2020 18:23:24
User entered 'Day 2'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-04T18:12:55', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '67a6eff3-e096-451a-a171-483c7ac13e42'	System	04 Sep 2020 22:13:38
User entered 'No interference with activity (1)'	System	04 Sep 2020 22:13:38

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-04T18:13:16', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '67a6eff3-e096-451a-a171-483c7ac13e42'	System	04 Sep 2020 22:13:38
User entered 'Some interference with activity (2)'	System	04 Sep 2020 22:13:38

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-04T18:13:22', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '67a6eff3-e096-451a-a171-483c7ac13e42'	System	04 Sep 2020 22:13:38
User entered 'None (0)'	System	04 Sep 2020 22:13:38

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-04T18:13:24', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '67a6eff3-e096-451a-a171-483c7ac13e42'	System	04 Sep 2020 22:13:38
User entered 'None (0)'	System	04 Sep 2020 22:13:38

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-04T18:13:27', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '67a6eff3-e096-451a-a171-483c7ac13e42'	System	04 Sep 2020 22:13:38
User entered 'None (0)'	System	04 Sep 2020 22:13:38

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-04T18:13:29', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '67a6eff3-e096-451a-a171-483c7ac13e42'	System	04 Sep 2020 22:13:38
User entered 'None (0)'	System	04 Sep 2020 22:13:38

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

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)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-04T18:13:32', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '67a6eff3-e096-451a-a171-483c7ac13e42'	System	04 Sep 2020 22:13:38
User entered 'No (N)'	System	04 Sep 2020 22:13:38

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-04T18:13:35', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '67a6eff3-e096-451a-a171-483c7ac13e42'	System	04 Sep 2020 22:13:38
User entered '04 Sep 2020 18:13'	System	04 Sep 2020 22:13:38

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	03 Sep 2020 18:23:24
User entered 'Day 3'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

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)	26 Feb 2021 04:23:38

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	03 Sep 2020 18:23:24
User entered 'Day 4'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-06T22:47:14', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f4c7e6d3-e313-43fc-a3d3-cb2510b73287'	System	07 Sep 2020 02:49:33
User entered 'No interference with activity (1)'	System	07 Sep 2020 02:49:33

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-06T22:47:22', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f4c7e6d3-e313-43fc-a3d3-cb2510b73287'	System	07 Sep 2020 02:49:33
User entered 'None (0)'	System	07 Sep 2020 02:49:33

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-06T22:48:39', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f4c7e6d3-e313-43fc-a3d3-cb2510b73287'	System	07 Sep 2020 02:49:33
User entered 'None (0)'	System	07 Sep 2020 02:49:33

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-06T22:49:09', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f4c7e6d3-e313-43fc-a3d3-cb2510b73287'	System	07 Sep 2020 02:49:33
User entered 'None (0)'	System	07 Sep 2020 02:49:33

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-06T22:49:17', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f4c7e6d3-e313-43fc-a3d3-cb2510b73287'	System	07 Sep 2020 02:49:33
User entered 'None (0)'	System	07 Sep 2020 02:49:33

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-06T22:49:19', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f4c7e6d3-e313-43fc-a3d3-cb2510b73287'	System	07 Sep 2020 02:49:33
User entered 'None (0)'	System	07 Sep 2020 02:49:33

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

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)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-06T22:49:27', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f4c7e6d3-e313-43fc-a3d3-cb2510b73287'	System	07 Sep 2020 02:49:33
User entered 'No (N)'	System	07 Sep 2020 02:49:33

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-06T22:49:30', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f4c7e6d3-e313-43fc-a3d3-cb2510b73287'	System	07 Sep 2020 02:49:33
User entered '06 Sep 2020 22:49'	System	07 Sep 2020 02:49:33

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	03 Sep 2020 18:23:24
User entered 'Day 5'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-07T13:36:06', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bcb3618a-1d5a-4bc4-9533-e29f61e10c2b'	System	07 Sep 2020 17:40:49
User entered 'None (0)'	System	07 Sep 2020 17:40:49

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-07T13:36:07', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bcb3618a-1d5a-4bc4-9533-e29f61e10c2b'	System	07 Sep 2020 17:40:49
User entered 'None (0)'	System	07 Sep 2020 17:40:49

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-07T13:36:10', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bcb3618a-1d5a-4bc4-9533-e29f61e10c2b'	System	07 Sep 2020 17:40:49
User entered 'None (0)'	System	07 Sep 2020 17:40:49

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-07T13:36:28', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bcb3618a-1d5a-4bc4-9533-e29f61e10c2b'	System	07 Sep 2020 17:40:49
User entered 'None (0)'	System	07 Sep 2020 17:40:49

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-07T13:37:20', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bcb3618a-1d5a-4bc4-9533-e29f61e10c2b'	System	07 Sep 2020 17:40:49
User entered 'None (0)'	System	07 Sep 2020 17:40:49

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-07T13:37:40', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bcb3618a-1d5a-4bc4-9533-e29f61e10c2b'	System	07 Sep 2020 17:40:49
User entered 'None (0)'	System	07 Sep 2020 17:40:49

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

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)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-07T13:38:11', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bcb3618a-1d5a-4bc4-9533-e29f61e10c2b'	System	07 Sep 2020 17:40:49
User entered 'No (N)'	System	07 Sep 2020 17:40:49

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-07T13:40:44', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bcb3618a-1d5a-4bc4-9533-e29f61e10c2b'	System	07 Sep 2020 17:40:49
User entered '07 Sep 2020 13:40'	System	07 Sep 2020 17:40:49

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	03 Sep 2020 18:23:24
User entered 'Day 6'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-08T14:35:31', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '3e661139-06c1-4249-a7bd-af8000376613'	System	08 Sep 2020 18:36:26
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	08 Sep 2020 18:36:26

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-08T14:35:39', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '3e661139-06c1-4249-a7bd-af8000376613'	System	08 Sep 2020 18:36:26
User entered 'No interference with activity (1)'	System	08 Sep 2020 18:36:26

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-08T14:35:46', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '3e661139-06c1-4249-a7bd-af8000376613'	System	08 Sep 2020 18:36:26
User entered 'No interference with activity (1)'	System	08 Sep 2020 18:36:26

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-08T14:35:48', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '3e661139-06c1-4249-a7bd-af8000376613'	System	08 Sep 2020 18:36:26
User entered 'None (0)'	System	08 Sep 2020 18:36:26

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-08T14:35:50', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '3e661139-06c1-4249-a7bd-af8000376613'	System	08 Sep 2020 18:36:26
User entered 'None (0)'	System	08 Sep 2020 18:36:26

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-08T14:35:53', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '3e661139-06c1-4249-a7bd-af8000376613'	System	08 Sep 2020 18:36:26
User entered 'None (0)'	System	08 Sep 2020 18:36:26

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

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)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-08T14:36:11', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '3e661139-06c1-4249-a7bd-af8000376613'	System	08 Sep 2020 18:36:26
User entered 'No (N)'	System	08 Sep 2020 18:36:26

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-08T14:36:22', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '3e661139-06c1-4249-a7bd-af8000376613'	System	08 Sep 2020 18:36:26
User entered '08 Sep 2020 14:36'	System	08 Sep 2020 18:36:26

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	03 Sep 2020 18:23:24
User entered 'Day 7'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-09T19:47:31', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '2ed13db5-044e-48c0-bfa2-413a59ca1118'	System	09 Sep 2020 23:48:13
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	09 Sep 2020 23:48:13

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-09T19:47:42', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '2ed13db5-044e-48c0-bfa2-413a59ca1118'	System	09 Sep 2020 23:48:13
User entered 'Significant; prevents daily activity (3)'	System	09 Sep 2020 23:48:13

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-09T19:47:52', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '2ed13db5-044e-48c0-bfa2-413a59ca1118'	System	09 Sep 2020 23:48:13
User entered 'None (0)'	System	09 Sep 2020 23:48:13

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-09T19:47:55', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '2ed13db5-044e-48c0-bfa2-413a59ca1118'	System	09 Sep 2020 23:48:13
User entered 'None (0)'	System	09 Sep 2020 23:48:13

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-09T19:47:57', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '2ed13db5-044e-48c0-bfa2-413a59ca1118'	System	09 Sep 2020 23:48:13
User entered 'None (0)'	System	09 Sep 2020 23:48:13

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-09T19:48:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '2ed13db5-044e-48c0-bfa2-413a59ca1118'	System	09 Sep 2020 23:48:13
User entered 'None (0)'	System	09 Sep 2020 23:48:13

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

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)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-09T19:48:03', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '2ed13db5-044e-48c0-bfa2-413a59ca1118'	System	09 Sep 2020 23:48:13
User entered 'No (N)'	System	09 Sep 2020 23:48:13

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-09T19:48:10', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '2ed13db5-044e-48c0-bfa2-413a59ca1118'	System	09 Sep 2020 23:48:13
User entered '09 Sep 2020 19:48'	System	09 Sep 2020 23:48:13

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 18:23:24

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	08 Sep 2020 18:36:26
User entered 'Day 8'	System	08 Sep 2020 18:36:26

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:05:41

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-10T21:40:10', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '0092a3dc-96ef-4476-8879-4104ca4bf1f9'	System	11 Sep 2020 01:40:19
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	11 Sep 2020 01:40:19

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-10T21:40:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '0092a3dc-96ef-4476-8879-4104ca4bf1f9'	System	11 Sep 2020 01:40:19
User entered '10 Sep 2020 21:40'	System	11 Sep 2020 01:40:19

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 18:36:26

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 18:36:26

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	09 Sep 2020 23:48:13
User entered 'Day 9'	System	09 Sep 2020 23:48:13

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:05:41

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-11T13:48:44', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '135fa283-ef9c-4b8a-848f-0078a3fbbdaa'	System	11 Sep 2020 17:48:49
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	11 Sep 2020 17:48:49

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-11T13:48:46', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '135fa283-ef9c-4b8a-848f-0078a3fbbdaa'	System	11 Sep 2020 17:48:49
User entered '11 Sep 2020 13:48'	System	11 Sep 2020 17:48:49

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 23:48:13

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 23:48:13

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	11 Sep 2020 01:40:19
User entered 'Day 10'	System	11 Sep 2020 01:40:19

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 11 Aug 2021 22:05:41

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-12T20:31:18', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e0bd88f4-41ee-4e17-92a8-f5a214f0d30d'	System	13 Sep 2020 00:31:25
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	13 Sep 2020 00:31:25

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-12T20:31:21', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e0bd88f4-41ee-4e17-92a8-f5a214f0d30d'	System	13 Sep 2020 00:31:25
User entered '12 Sep 2020 20:31'	System	13 Sep 2020 00:31:25

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 01:40:19

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 01:40:19

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(11)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	11 Sep 2020 17:48:49
User entered 'Day 11'	System	11 Sep 2020 17:48:49

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(11)

Generated On: 11 Aug 2021 22:05:41

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-13T18:58:31', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '7f5b24c9-e4ca-4ca9-9e19-48ca62a8a655'	System	13 Sep 2020 22:58:35
User entered 'None (0)'	System	13 Sep 2020 22:58:35

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(11)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-13T18:58:33', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '7f5b24c9-e4ca-4ca9-9e19-48ca62a8a655'	System	13 Sep 2020 22:58:35
User entered '13 Sep 2020 18:58'	System	13 Sep 2020 22:58:35

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(11)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 17:48:49

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(11)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 17:48:49

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	08 Sep 2020 18:36:26
User entered 'Day 8'	System	08 Sep 2020 18:36:26

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:05:41

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-10T21:40:34', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'd20ad97c-4336-4c20-97de-c877cca77022'	System	11 Sep 2020 01:40:41
User entered 'Significant; prevents daily activity (3)'	System	11 Sep 2020 01:40:41

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-10T21:40:36', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'd20ad97c-4336-4c20-97de-c877cca77022'	System	11 Sep 2020 01:40:41
User entered '10 Sep 2020 21:40'	System	11 Sep 2020 01:40:41

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 18:36:26

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 18:36:26

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	09 Sep 2020 23:48:13
User entered 'Day 9'	System	09 Sep 2020 23:48:13

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:05:41

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-11T14:30:46', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f88ed07b-e3a7-4c76-8ad4-56b8c99b4847'	System	11 Sep 2020 18:30:53
User entered 'Some interference with activity (2)'	System	11 Sep 2020 18:30:53

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-11T14:30:48', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f88ed07b-e3a7-4c76-8ad4-56b8c99b4847'	System	11 Sep 2020 18:30:53
User entered '11 Sep 2020 14:30'	System	11 Sep 2020 18:30:53

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 23:48:13

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 23:48:13

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	11 Sep 2020 01:40:41
User entered 'Day 10'	System	11 Sep 2020 01:40:41

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 11 Aug 2021 22:05:41

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-12T20:31:35', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '0fae4403-e136-4024-b8cf-b57edab67f24'	System	13 Sep 2020 00:31:40
User entered 'Some interference with activity (2)'	System	13 Sep 2020 00:31:40

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-12T20:31:38', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '0fae4403-e136-4024-b8cf-b57edab67f24'	System	13 Sep 2020 00:31:40
User entered '12 Sep 2020 20:31'	System	13 Sep 2020 00:31:40

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 01:40:41

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 01:40:41

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	11 Sep 2020 18:30:53
User entered 'Day 11'	System	11 Sep 2020 18:30:53

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 11 Aug 2021 22:05:41

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-13T18:58:37', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e4864d99-0389-4003-9c49-ffbd1a832066'	System	13 Sep 2020 22:58:44
User entered 'None (0)'	System	13 Sep 2020 22:58:44

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-13T18:58:39', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e4864d99-0389-4003-9c49-ffbd1a832066'	System	13 Sep 2020 22:58:44
User entered '13 Sep 2020 18:58'	System	13 Sep 2020 22:58:44

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 18:30:53

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 18:30:53

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	08 Sep 2020 18:35:20
User entered 'Day 8'	System	08 Sep 2020 18:35:20

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:05:41

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)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-10T21:41:11', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '33e24e57-428f-4cb6-8c77-3c3dc0c6cc83'	System	11 Sep 2020 01:41:19
User entered 'Yes (Y)'	System	11 Sep 2020 01:41:19

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-10T21:41:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '33e24e57-428f-4cb6-8c77-3c3dc0c6cc83'	System	11 Sep 2020 01:41:19
User entered '10 Sep 2020 21:41'	System	11 Sep 2020 01:41:19

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 18:35:20

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 18:35:20

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	09 Sep 2020 23:46:10
User entered 'Day 9'	System	09 Sep 2020 23:46:10

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:05:41

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)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-11T14:31:05', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f982c5d7-1f09-41e1-a1c3-5d836495269b'	System	11 Sep 2020 18:31:12
User entered 'No (N)'	System	11 Sep 2020 18:31:12

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-11T14:31:07', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f982c5d7-1f09-41e1-a1c3-5d836495269b'	System	11 Sep 2020 18:31:12
User entered '11 Sep 2020 14:31'	System	11 Sep 2020 18:31:12

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 23:46:10

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 23:46:10

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	11 Sep 2020 01:40:19
User entered 'Day 10'	System	11 Sep 2020 01:40:19

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:05:41

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)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-12T20:31:51', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'a3470764-8422-4555-9f19-15cfd09e8b2a'	System	13 Sep 2020 00:31:59
User entered 'No (N)'	System	13 Sep 2020 00:31:59

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-12T20:31:54', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'a3470764-8422-4555-9f19-15cfd09e8b2a'	System	13 Sep 2020 00:31:59
User entered '12 Sep 2020 20:31'	System	13 Sep 2020 00:31:59

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 01:40:19

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 01:40:19

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	11 Sep 2020 17:48:49
User entered 'Day 11'	System	11 Sep 2020 17:48:49

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:05:41

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)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-13T18:58:43', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '4bffe25f-850e-41f2-b52e-e36be4d25bde'	System	13 Sep 2020 22:58:52
User entered 'No (N)'	System	13 Sep 2020 22:58:52

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-13T18:58:45', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '4bffe25f-850e-41f2-b52e-e36be4d25bde'	System	13 Sep 2020 22:58:52
User entered '13 Sep 2020 18:58'	System	13 Sep 2020 22:58:52

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 17:48:49

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 17:48:49

US3202057

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:43:54

US3202057

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:43:54

US3202057

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:43:54

US3202057

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	(b) (4)	16 Sep 2020 16:44:09
Please review and reconcile.' (Site from System).	System	
User entered 'contact attempted 10 Sep and 11 Sep' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 16:44:09
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	System	16 Sep 2020 16:43:54
Please review and reconcile.' (Site from System).		
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 16:43:54

US3202057

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:44:14

US3202057

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered '1'	System	16 Sep 2020 16:44:14

US3202057

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	18 Sep 2020 16:44:18
	(b) (4)	

US3202057

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '18 Sep 2020'	(b) (4) zackery harmon (b) (4)	18 Sep 2020 16:44:18
	(b) (4)	

US3202057

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) zackery harmon (b) (4)	18 Sep 2020 16:44:18

US3202057

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered empty.	(b) (4) zackery harmon (b) (4)	18 Sep 2020 16:44:18
	(b) (4)	

US3202057

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 15:23:37

US3202057

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered '1'	System	02 Oct 2020 15:23:37

US3202057

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	02 Oct 2020 20:27:32

US3202057

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered '24 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	02 Oct 2020 20:27:32

US3202057

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Tiffany Jewell (b) (4)	02 Oct 2020 20:27:32

US3202057

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	02 Oct 2020 20:27:32

US3202057

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:15
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 15:23:43

US3202057

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered '1'	System	02 Oct 2020 15:23:43

US3202057

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:31:37
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 15:23:54

US3202057

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:31:37
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User entered '2 Oct 2020'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 15:23:54

US3202057

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:31:37
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User entered 'Clinic (Clinic)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 15:23:54

US3202057

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:31:37
User entered 'VISIT3'	System	02 Oct 2020 15:23:54

US3202057

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:31:37
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	02 Oct 2020 20:29:19
	(b) (4)	

US3202057

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:31:37
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User entered '2 Oct 2020'	(b) (4) Tiffany Jewell (b) (4)	02 Oct 2020 20:29:19

US3202057

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:31:37
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User entered '11:34'	(b) (4) Tiffany Jewell (b) (4)	02 Oct 2020 20:29:19

US3202057

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:31:37
User entered '2 Oct 2020 11:34'	System	02 Oct 2020 20:29:19

US3202057

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:31:37
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User entered '36.9' C	(b) (4) Tiffany Jewell (b) (4)	02 Oct 2020 20:29:19

US3202057

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:31:37
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User entered 'Oral (Oral)'	(b) (4) Tiffany Jewell (b) (4)	02 Oct 2020 20:29:19
	(b) (4)	

US3202057

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:31:37
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	02 Oct 2020 20:29:19
	(b) (4)	

US3202057

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:31:37
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User entered '70'	(b) (4) Tiffany Jewell (b) (4)	02 Oct 2020 20:29:19

US3202057

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:31:37
User entered 'bpm'	System	02 Oct 2020 20:29:19

US3202057

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:31:37
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User entered '16'	(b) (4) Tiffany Jewell (b) (4)	02 Oct 2020 20:29:19

US3202057

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:31:37
User entered 'breaths/min'	System	02 Oct 2020 20:29:19

US3202057

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:31:37
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User entered '101'	(b) (4) Tiffany Jewell (b) (4)	02 Oct 2020 20:29:19

US3202057

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:31:37
User entered 'mmHg'	System	02 Oct 2020 20:29:19

US3202057

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:31:37
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User entered '64'	(b) (4) Tiffany Jewell (b) (4)	02 Oct 2020 20:29:19

US3202057

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:31:37
User entered 'mmHg'	System	02 Oct 2020 20:29:19

US3202057

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:31:37

US3202057

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:31:37

US3202057

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:31:37
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	02 Oct 2020 20:29:25

US3202057

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:31:37
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	02 Oct 2020 20:29:25

US3202057

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:31:37
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	02 Oct 2020 20:31:04

US3202057

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:31:37
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User entered '2 Oct 2020'	(b) (4) Tiffany Jewell (b) (4)	02 Oct 2020 20:31:04

US3202057

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:31:37
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User entered '11:48'	(b) (4) Tiffany Jewell (b) (4)	02 Oct 2020 20:31:04

US3202057

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:31:37
User entered '2 Oct 2020 11:48'	System	02 Oct 2020 20:31:04

US3202057

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:52:17
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	02 Oct 2020 20:31:09

US3202057

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered '1'	System	02 Oct 2020 20:31:09

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered 'Day 64'	System	07 Aug 2020 20:19:38

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[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)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:41:59', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b'	System	07 Oct 2020 16:43:38
User entered 'Yes (Y)'	System	07 Oct 2020 16:43:38

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with 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)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:42:09', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b'	System	07 Oct 2020 16:43:38
User entered 'No (N)'	System	07 Oct 2020 16:43:38

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:42:13', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b'	System	07 Oct 2020 16:43:38
User entered 'Yes (Y)'	System	07 Oct 2020 16:43:38

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:43:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b'	System	07 Oct 2020 16:43:38
User entered '0'	System	07 Oct 2020 16:43:38

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:43:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b'	System	07 Oct 2020 16:43:38
User entered '0'	System	07 Oct 2020 16:43:38

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:43:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b'	System	07 Oct 2020 16:43:38
User entered '0'	System	07 Oct 2020 16:43:38

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:43:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b'	System	07 Oct 2020 16:43:38
User entered '0'	System	07 Oct 2020 16:43:38

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:43:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b'	System	07 Oct 2020 16:43:38
User entered '0'	System	07 Oct 2020 16:43:38

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:43:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b'	System	07 Oct 2020 16:43:38
User entered '0'	System	07 Oct 2020 16:43:38

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:43:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b'	System	07 Oct 2020 16:43:38
User entered '1'	System	07 Oct 2020 16:43:38

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:43:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b'	System	07 Oct 2020 16:43:38
User entered '0'	System	07 Oct 2020 16:43:38

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:43:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b'	System	07 Oct 2020 16:43:38
User entered '1'	System	07 Oct 2020 16:43:38

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:43:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b'	System	07 Oct 2020 16:43:38
User entered '0'	System	07 Oct 2020 16:43:38

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:43:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b'	System	07 Oct 2020 16:43:38
User entered '0'	System	07 Oct 2020 16:43:38

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:43:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b'	System	07 Oct 2020 16:43:38
User entered '0'	System	07 Oct 2020 16:43:38

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:43:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b'	System	07 Oct 2020 16:43:38
User entered '0'	System	07 Oct 2020 16:43:38

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:43:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b'	System	07 Oct 2020 16:43:38
User entered '0'	System	07 Oct 2020 16:43:38

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:43:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b'	System	07 Oct 2020 16:43:38
User entered '0'	System	07 Oct 2020 16:43:38

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:43:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b'	System	07 Oct 2020 16:43:38
User entered '1'	System	07 Oct 2020 16:43:38

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:43:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b'	System	07 Oct 2020 16:43:38
User entered '1'	System	07 Oct 2020 16:43:38

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Please 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)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:43:16', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b'	System	07 Oct 2020 16:43:38
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Oct 2020 16:43:38

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:43:24', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b'	System	07 Oct 2020 16:43:38
User entered 'No (N)'	System	07 Oct 2020 16:43:38

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:43:27', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b' User entered '07 Oct 2020 12:43:27'	System	07 Oct 2020 16:43:38
	System	07 Oct 2020 16:43:38

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered '07 Oct 2020 00:01'	System	07 Aug 2020 20:19:38

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered '11 Oct 2020 23:59'	System	07 Aug 2020 20:19:38

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered 'Day 71'	System	07 Aug 2020 20:19:38

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[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)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-14T07:23:37', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '97f59919-18a4-4815-932f-337fb0bf6f02'	System	14 Oct 2020 11:24:05
User entered 'Yes (Y)'	System	14 Oct 2020 11:24:05

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with 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)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-14T07:23:41', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '97f59919-18a4-4815-932f-337fb0bf6f02'	System	14 Oct 2020 11:24:05
User entered 'No (N)'	System	14 Oct 2020 11:24:05

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-14T07:23:49', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '97f59919-18a4-4815-932f-337fb0bf6f02'	System	14 Oct 2020 11:24:05
User entered 'No (N)'	System	14 Oct 2020 11:24:05

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-14T07:23:57', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '97f59919-18a4-4815-932f-337fb0bf6f02'	System	14 Oct 2020 11:24:05
User entered 'No (N)'	System	14 Oct 2020 11:24:05

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-14T07:24:02', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '97f59919-18a4-4815-932f-337fb0bf6f02'	System	14 Oct 2020 11:24:05
User entered '14 Oct 2020 07:24:02'	System	14 Oct 2020 11:24:05

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered '14 Oct 2020 00:01'	System	07 Aug 2020 20:19:38

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered '18 Oct 2020 23:59'	System	07 Aug 2020 20:19:38

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered 'Day 78'	System	07 Aug 2020 20:19:38

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[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)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-21T12:34:37', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ab46a2f6-72a3-4fe8-9623-14b736e98d9e'	System	21 Oct 2020 16:34:52
User entered 'No (N)'	System	21 Oct 2020 16:34:52

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with 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)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-21T12:34:42', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ab46a2f6-72a3-4fe8-9623-14b736e98d9e'	System	21 Oct 2020 16:34:52
User entered 'No (N)'	System	21 Oct 2020 16:34:52

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-21T12:34:49', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ab46a2f6-72a3-4fe8-9623-14b736e98d9e' User entered '21 Oct 2020 12:34:49'	System	21 Oct 2020 16:34:52
	System	21 Oct 2020 16:34:52

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered '21 Oct 2020 00:01'	System	07 Aug 2020 20:19:38

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered '25 Oct 2020 23:59'	System	07 Aug 2020 20:19:38

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered 'Day 92'	System	07 Aug 2020 20:19:38

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-11-06T15:07:26', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '240088a6-c959-4ebc-bde5-f35d416eb1be'	System	06 Nov 2020 20:07:57
User entered 'No (N)'	System	06 Nov 2020 20:07:57

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with 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)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-11-06T15:07:36', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '240088a6-c959-4ebc-bde5-f35d416eb1be'	System	06 Nov 2020 20:07:57
User entered 'Yes (Y)'	System	06 Nov 2020 20:07:57

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Please 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)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-11-06T15:07:40', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '240088a6-c959-4ebc-bde5-f35d416eb1be'	System	06 Nov 2020 20:07:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Nov 2020 20:07:57

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-11-06T15:07:45', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '240088a6-c959-4ebc-bde5-f35d416eb1be' User entered '06 Nov 2020 15:07:45'	System	06 Nov 2020 20:07:57
	System	06 Nov 2020 20:07:57

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered '04 Nov 2020 00:01'	System	07 Aug 2020 20:19:38

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered '08 Nov 2020 23:59'	System	07 Aug 2020 20:19:38

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered 'Day 99'	System	07 Aug 2020 20:19:38

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[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)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-11-13T02:10:28', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'd7c95173-ec9a-403c-b22e-40464bc070ba'	System	13 Nov 2020 07:10:41
User entered 'No (N)'	System	13 Nov 2020 07:10:41

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with 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)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-11-13T02:10:34', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'd7c95173-ec9a-403c-b22e-40464bc070ba'	System	13 Nov 2020 07:10:41
User entered 'No (N)'	System	13 Nov 2020 07:10:41

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-11-13T02:10:38', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'd7c95173-ec9a-403c-b22e-40464bc070ba' User entered '13 Nov 2020 02:10:38'	System	13 Nov 2020 07:10:41
	System	13 Nov 2020 07:10:41

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered '11 Nov 2020 00:01'	System	07 Aug 2020 20:19:38

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered '15 Nov 2020 23:59'	System	07 Aug 2020 20:19:38

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered 'Day 106'	System	07 Aug 2020 20:19:38

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-11-18T14:16:41', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ddb79b2e-0006-4ea7-aeb7-de76e843cda3'	System	18 Nov 2020 19:16:48
User entered 'No (N)'	System	18 Nov 2020 19:16:48

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with 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)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-11-18T14:16:43', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ddb79b2e-0006-4ea7-aeb7-de76e843cda3'	System	18 Nov 2020 19:16:48
User entered 'No (N)'	System	18 Nov 2020 19:16:48

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-11-18T14:16:46', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ddb79b2e-0006-4ea7-aeb7-de76e843cda3'	System	18 Nov 2020 19:16:48
User entered '18 Nov 2020 14:16:46'	System	18 Nov 2020 19:16:48

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered '18 Nov 2020 00:01'	System	07 Aug 2020 20:19:38

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:23:38
Data entry locked.	System	07 Aug 2020 20:19:38
User entered '22 Nov 2020 23:59'	System	07 Aug 2020 20:19:38

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-11-25T05:13:53', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '6ffecf00-0157-40ac-8d80-5e151dcb1a94'	System	25 Nov 2020 10:14:03
User entered 'No (N)'	System	25 Nov 2020 10:14:03

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-11-25T05:13:57', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '6ffecf00-0157-40ac-8d80-5e151dcb1a94'	System	25 Nov 2020 10:14:03
User entered 'No (N)'	System	25 Nov 2020 10:14:03

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-11-25T05:14:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '6ffecf00-0157-40ac-8d80-5e151dcb1a94'	System	25 Nov 2020 10:14:03
User entered '25 Nov 2020 05:14:00'	System	25 Nov 2020 10:14:03

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-12-02T09:28:19', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '943acf51-4b62-4b96-8b6f-083c24810fd4'	System	02 Dec 2020 14:28:34
User entered 'No (N)'	System	02 Dec 2020 14:28:34

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-12-02T09:28:26', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '943acf51-4b62-4b96-8b6f-083c24810fd4'	System	02 Dec 2020 14:28:34
User entered 'No (N)'	System	02 Dec 2020 14:28:34

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-12-02T09:28:31', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '943acf51-4b62-4b96-8b6f-083c24810fd4'	System	02 Dec 2020 14:28:34
User entered '02 Dec 2020 09:28:31'	System	02 Dec 2020 14:28:34

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-12-08T20:07:42', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'af15d3b3-13b2-46ec-b528-896ffafa3ed9'	System	09 Dec 2020 01:07:50
User entered 'No (N)'	System	09 Dec 2020 01:07:50

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-12-08T20:07:44', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'af15d3b3-13b2-46ec-b528-896ffafa3ed9'	System	09 Dec 2020 01:07:50
User entered 'No (N)'	System	09 Dec 2020 01:07:50

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-12-08T20:07:47', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'af15d3b3-13b2-46ec-b528-896ffafa3ed9' User entered '08 Dec 2020 20:07:47'	System	09 Dec 2020 01:07:50
	System	09 Dec 2020 01:07:50

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-12-16T14:38:09', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '56cdf41-5c42-458d-8adc-a6295a70496f'	System	16 Dec 2020 19:38:24
User entered 'No (N)'	System	16 Dec 2020 19:38:24

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-12-16T14:38:12', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '56cdf41-5c42-458d-8adc-a6295a70496f'	System	16 Dec 2020 19:38:24
User entered 'No (N)'	System	16 Dec 2020 19:38:24

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-12-16T14:38:18', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '56cdf41-5c42-458d-8adc-a6295a70496f' User entered '16 Dec 2020 14:38:18'	System	16 Dec 2020 19:38:24
	System	16 Dec 2020 19:38:24

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-12-20T11:42:11', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1dc1389b-801f-41e4-8042-6ba2de747b07'	System	20 Dec 2020 16:42:20
User entered 'No (N)'	System	20 Dec 2020 16:42:20

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-12-20T11:42:13', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1dc1389b-801f-41e4-8042-6ba2de747b07'	System	20 Dec 2020 16:42:20
User entered 'No (N)'	System	20 Dec 2020 16:42:20

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-12-20T11:42:17', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1dc1389b-801f-41e4-8042-6ba2de747b07'	System	20 Dec 2020 16:42:20
User entered '20 Dec 2020 11:42:17'	System	20 Dec 2020 16:42:20

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-12-29T16:18:30', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ce7c4683-7051-406d-9335-f608cf2edefc'	System	29 Dec 2020 21:18:39
User entered 'No (N)'	System	29 Dec 2020 21:18:39

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-12-29T16:18:34', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ce7c4683-7051-406d-9335-f608cf2edefc'	System	29 Dec 2020 21:18:39
User entered 'No (N)'	System	29 Dec 2020 21:18:39

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-12-29T16:18:35', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ce7c4683-7051-406d-9335-f608cf2edefc'	System	29 Dec 2020 21:18:39
User entered '29 Dec 2020 16:18:35'	System	29 Dec 2020 21:18:39

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-01-05T04:07:50', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '3af35686-61e4-41cb-aaaa-f5fa2a6712d1'	System	05 Jan 2021 09:07:59
User entered 'No (N)'	System	05 Jan 2021 09:07:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-01-05T04:07:52', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '3af35686-61e4-41cb-aaaa-f5fa2a6712d1'	System	05 Jan 2021 09:07:59
User entered 'No (N)'	System	05 Jan 2021 09:07:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-01-05T04:07:55', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '3af35686-61e4-41cb-aaaa-f5fa2a6712d1'	System	05 Jan 2021 09:07:59
User entered '05 Jan 2021 04:07:55'	System	05 Jan 2021 09:07:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-01-14T18:32:52', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'c7cede16-70bc-41be-80b3-f9b8896f67fc'	System	14 Jan 2021 23:33:05
User entered 'No (N)'	System	14 Jan 2021 23:33:05

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-01-14T18:32:58', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'c7cede16-70bc-41be-80b3-f9b8896f67fc'	System	14 Jan 2021 23:33:05
User entered 'No (N)'	System	14 Jan 2021 23:33:05

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-01-14T18:33:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'c7cede16-70bc-41be-80b3-f9b8896f67fc' User entered '14 Jan 2021 18:33:00'	System	14 Jan 2021 23:33:05
	System	14 Jan 2021 23:33:05

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-01-18T23:02:25', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9c075677-6b8f-454a-8cb4-f627bc64639c'	System	19 Jan 2021 04:02:32
User entered 'No (N)'	System	19 Jan 2021 04:02:32

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-01-18T23:02:27', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9c075677-6b8f-454a-8cb4-f627bc64639c'	System	19 Jan 2021 04:02:32
User entered 'No (N)'	System	19 Jan 2021 04:02:32

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-01-18T23:02:28', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9c075677-6b8f-454a-8cb4-f627bc64639c'	System	19 Jan 2021 04:02:32
User entered '18 Jan 2021 23:02:28'	System	19 Jan 2021 04:02:32

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-01-27T06:25:56', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'a0bb7be1-2abd-4e0e-bf4e-8465eb55e243'	System	27 Jan 2021 11:26:04
User entered 'No (N)'	System	27 Jan 2021 11:26:04

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-01-27T06:25:58', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'a0bb7be1-2abd-4e0e-bf4e-8465eb55e243'	System	27 Jan 2021 11:26:04
User entered 'No (N)'	System	27 Jan 2021 11:26:04

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-01-27T06:25:59', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'a0bb7be1-2abd-4e0e-bf4e-8465eb55e243' User entered '27 Jan 2021 06:25:59'	System	27 Jan 2021 11:26:04
	System	27 Jan 2021 11:26:04

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-02-03T23:33:24', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '060060d8-1473-4611-aa9f-2cc04f636ea5'	System	04 Feb 2021 04:33:33
User entered 'No (N)'	System	04 Feb 2021 04:33:33

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-02-03T23:33:26', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '060060d8-1473-4611-aa9f-2cc04f636ea5'	System	04 Feb 2021 04:33:33
User entered 'No (N)'	System	04 Feb 2021 04:33:33

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-02-03T23:33:28', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '060060d8-1473-4611-aa9f-2cc04f636ea5'	System	04 Feb 2021 04:33:33
User entered '03 Feb 2021 23:33:28'	System	04 Feb 2021 04:33:33

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-02-08T12:20:30', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'a2a46f54-424f-4c1d-a1ac-3d3371dca864'	System	08 Feb 2021 17:20:40
User entered 'No (N)'	System	08 Feb 2021 17:20:40

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-02-08T12:20:32', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'a2a46f54-424f-4c1d-a1ac-3d3371dca864'	System	08 Feb 2021 17:20:40
User entered 'No (N)'	System	08 Feb 2021 17:20:40

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-02-08T12:20:37', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'a2a46f54-424f-4c1d-a1ac-3d3371dca864'	System	08 Feb 2021 17:20:40
User entered '08 Feb 2021 12:20:37'	System	08 Feb 2021 17:20:40

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-02-15T15:41:20', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '190ecac1-4201-4840-86f7-1df770e7f27f' User entered 'No (N)'	System	15 Feb 2021 20:41:27
	System	15 Feb 2021 20:41:27

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-02-15T15:41:22', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '190ecac1-4201-4840-86f7-1df770e7f27f' User entered 'No (N)'	System	15 Feb 2021 20:41:27

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-02-15T15:41:24', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '190ecac1-4201-4840-86f7-1df770e7f27f'	System	15 Feb 2021 20:41:27
User entered '15 Feb 2021 15:41:24'	System	15 Feb 2021 20:41:27

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-02-21T08:49:16', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '60e1c453-e9cf-40f8-a00c-82d516227865'	System	21 Feb 2021 13:49:23
User entered 'No (N)'	System	21 Feb 2021 13:49:23

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-02-21T08:49:17', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '60e1c453-e9cf-40f8-a00c-82d516227865'	System	21 Feb 2021 13:49:23
User entered 'No (N)'	System	21 Feb 2021 13:49:23

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-02-21T08:49:21', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '60e1c453-e9cf-40f8-a00c-82d516227865'	System	21 Feb 2021 13:49:23
User entered '21 Feb 2021 08:49:21'	System	21 Feb 2021 13:49:23

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-03-02T02:15:49-05:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '3535bb8a-60a3-4418-afdc-92495e0acf6d'	System	02 Mar 2021 07:15:57
User entered 'No (N)'	System	02 Mar 2021 07:15:57

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-03-02T02:15:51-05:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '3535bb8a-60a3-4418-afdc-92495e0acf6d'	System	02 Mar 2021 07:15:57
User entered 'No (N)'	System	02 Mar 2021 07:15:57

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-03-02T02:15:54-05:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '3535bb8a-60a3-4418-afdc-92495e0acf6d' User entered '02 Mar 2021 02:15:54'	System	02 Mar 2021 07:15:57
	System	02 Mar 2021 07:15:57

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-03-08T02:56:14-05:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'd0c95498-0a3f-4f4c-9b76-2d0b0ee1b479'	System	08 Mar 2021 07:56:21
User entered 'No (N)'	System	08 Mar 2021 07:56:21

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-03-08T02:56:16-05:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'd0c95498-0a3f-4f4c-9b76-2d0b0ee1b479'	System	08 Mar 2021 07:56:21
User entered 'No (N)'	System	08 Mar 2021 07:56:21

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-03-08T02:56:18-05:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'd0c95498-0a3f-4f4c-9b76-2d0b0ee1b479' User entered '08 Mar 2021 02:56:18'	System	08 Mar 2021 07:56:21
	System	08 Mar 2021 07:56:21

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-03-15T03:20:48-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '34aaf857-c95b-4cbe-abb5-53696326ed00'	System	15 Mar 2021 07:20:56
User entered 'No (N)'	System	15 Mar 2021 07:20:56

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-03-15T03:20:50-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '34aaf857-c95b-4cbe-abb5-53696326ed00'	System	15 Mar 2021 07:20:56
User entered 'No (N)'	System	15 Mar 2021 07:20:56

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-03-15T03:20:53-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '34aaf857-c95b-4cbe-abb5-53696326ed00' User entered '15 Mar 2021 03:20:53'	System	15 Mar 2021 07:20:56
	System	15 Mar 2021 07:20:56

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-03-21T18:32:14-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e3c59d65-44e8-4960-93c4-b4af2aeea255'	System	21 Mar 2021 22:32:42
User entered 'No (N)'	System	21 Mar 2021 22:32:42

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-03-21T18:32:16-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e3c59d65-44e8-4960-93c4-b4af2aeea255'	System	21 Mar 2021 22:32:42
User entered 'No (N)'	System	21 Mar 2021 22:32:42

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-03-21T18:32:38-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e3c59d65-44e8-4960-93c4-b4af2aeea255'	System	21 Mar 2021 22:32:42
User entered '21 Mar 2021 18:32:38'	System	21 Mar 2021 22:32:42

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-03-28T06:04:44-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '4e943683-b9ae-4de5-9813-024a0d91faa4'	System	28 Mar 2021 10:05:07
User entered 'No (N)'	System	28 Mar 2021 10:05:07

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-03-28T06:04:37-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '4e943683-b9ae-4de5-9813-024a0d91faa4'	System	28 Mar 2021 10:05:07
User entered 'No (N)'	System	28 Mar 2021 10:05:07

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-03-28T06:05:03-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '4e943683-b9ae-4de5-9813-024a0d91faa4' User entered '28 Mar 2021 06:05:03'	System	28 Mar 2021 10:05:07
	System	28 Mar 2021 10:05:07

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-04-05T07:29:45-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e0bcf000-dce2-4312-87b0-6adbd74e8a1a'	System	05 Apr 2021 11:29:53
User entered 'No (N)'	System	05 Apr 2021 11:29:53

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-04-05T07:29:46-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e0bcf000-dce2-4312-87b0-6adbd74e8a1a'	System	05 Apr 2021 11:29:53
User entered 'No (N)'	System	05 Apr 2021 11:29:53

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-04-05T07:29:48-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e0bcf000-dce2-4312-87b0-6adbd74e8a1a' User entered '05 Apr 2021 07:29:48'	System	05 Apr 2021 11:29:53
	System	05 Apr 2021 11:29:53

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-04-12T09:23:07-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ddf7ff1e-b9ee-46b9-9a8d-1a1c9f045229'	System	12 Apr 2021 13:23:16
User entered 'No (N)'	System	12 Apr 2021 13:23:16

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-04-12T09:23:11-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ddf7ff1e-b9ee-46b9-9a8d-1a1c9f045229'	System	12 Apr 2021 13:23:16
User entered 'No (N)'	System	12 Apr 2021 13:23:16

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-04-12T09:23:13-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ddf7ff1e-b9ee-46b9-9a8d-1a1c9f045229'	System	12 Apr 2021 13:23:16
User entered '12 Apr 2021 09:23:13'	System	12 Apr 2021 13:23:16

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-04-18T18:10:52-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '87628fa6-8e9c-400c-b952-fe21eccc4232'	System	18 Apr 2021 22:10:59
User entered 'No (N)'	System	18 Apr 2021 22:10:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-04-18T18:10:54-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '87628fa6-8e9c-400c-b952-fe21eccc4232'	System	18 Apr 2021 22:10:59
User entered 'No (N)'	System	18 Apr 2021 22:10:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-04-18T18:10:56-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '87628fa6-8e9c-400c-b952-fe21eccc4232'	System	18 Apr 2021 22:10:59
User entered '18 Apr 2021 18:10:56'	System	18 Apr 2021 22:10:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-04-26T12:30:55-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '8a76fc82-89d6-4b9f-b7fe-26457b4efc34'	System	26 Apr 2021 16:31:37
User entered 'Yes (Y)'	System	26 Apr 2021 16:31:37

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-04-26T12:30:59-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '8a76fc82-89d6-4b9f-b7fe-26457b4efc34'	System	26 Apr 2021 16:31:37
User entered 'No (N)'	System	26 Apr 2021 16:31:37

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-04-26T12:31:02-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '8a76fc82-89d6-4b9f-b7fe-26457b4efc34'	System	26 Apr 2021 16:31:37
User entered 'No (N)'	System	26 Apr 2021 16:31:37

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-04-26T12:31:15-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '8a76fc82-89d6-4b9f-b7fe-26457b4efc34'	System	26 Apr 2021 16:31:37
User entered 'Yes (Y)'	System	26 Apr 2021 16:31:37

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-04-26T12:31:21-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '8a76fc82-89d6-4b9f-b7fe-26457b4efc34'	System	26 Apr 2021 16:31:37
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	26 Apr 2021 16:31:37

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-04-26T12:31:24-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '8a76fc82-89d6-4b9f-b7fe-26457b4efc34'	System	26 Apr 2021 16:31:37
User entered '26 Apr 2021 12:31:24'	System	26 Apr 2021 16:31:37

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 16:03:44

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:03:44
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 16:03:44

US3202057

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:05:41

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:00:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-03-02T04:02:27-05:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '3af64156-fe86-4e94-b5e1-06fab868a764'	System	02 Mar 2021 09:03:45
User entered 'No (N)'	System	02 Mar 2021 09:03:45

US3202057

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:05:41

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:00:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-03-02T04:03:42-05:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '3af64156-fe86-4e94-b5e1-06fab868a764'	System	02 Mar 2021 09:03:45
User entered '02 Mar 2021 04:03:42'	System	02 Mar 2021 09:03:45

US3202057

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:38:09
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	20 Nov 2020 14:40:43
	(b) (4)	

US3202057

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:38:09
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 09:25:58
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'PD noted OOW' (Site from System).	zackery harmon (b) (4) (b) (4)	20 Nov 2020 14:43:04
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	20 Nov 2020 14:40:43
User entered '03 Nov 2020'	zackery harmon (b) (4) (b) (4)	20 Nov 2020 14:40:43

US3202057

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:38:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) zackery harmon (b) (4)	20 Nov 2020 14:40:43
	(b) (4)	

US3202057

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:38:09
User entered empty.	(b) (4) zackery harmon (b) (4)	20 Nov 2020 14:40:43
	(b) (4)	

US3202057

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:38:09
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	20 Nov 2020 14:43:14
	(b) (4)	

US3202057

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:30:50
User entered '1'	System	20 Nov 2020 14:43:14

US3202057

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:27:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:30:11

US3202057

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:27:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '2 Dec 2020'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:30:11

US3202057

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:27:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:30:11

US3202057

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:27:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:30:11

US3202057

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:27:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:30:14

US3202057

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:27:01
User entered '1'	System	02 Dec 2020 14:30:14

US3202057

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:27:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	01 Jan 2021 16:22:14
	(b) (4)	

US3202057

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:27:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '01 Jan 2021'	(b) (4) zackery harmon (b) (4)	01 Jan 2021 16:22:14
	(b) (4)	

US3202057

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:27:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) zackery harmon (b) (4)	01 Jan 2021 16:22:14

US3202057

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:27:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) zackery harmon (b) (4)	01 Jan 2021 16:22:14

US3202057

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:27:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	01 Jan 2021 16:22:18
	(b) (4)	

US3202057

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:27:01
User entered '1'	System	01 Jan 2021 16:22:18

US3202057

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:27:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	02 Feb 2021 13:34:16
	(b) (4)	

US3202057

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:27:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '01 Feb 2021'	(b) (4) zackery harmon (b) (4)	02 Feb 2021 13:34:16
	(b) (4)	

US3202057

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:27:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) zackery harmon (b) (4)	02 Feb 2021 13:34:16

US3202057

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:27:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) zackery harmon (b) (4)	02 Feb 2021 13:34:16

US3202057

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:27:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	11 Feb 2021 18:48:08
	(b) (4)	

US3202057

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:27:01
User entered '1'	System	11 Feb 2021 18:48:08

US3202057

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:16:59
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	Lilian Nukuna (b) (4)	02 Mar 2021 21:38:45

US3202057

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:16:59
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '2 Mar 2021'	Lilian Nukuna (b) (4)	02 Mar 2021 21:38:45

US3202057

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:16:59
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Clinic (Clinic)'	Lilian Nukuna (b) (4)	02 Mar 2021 21:38:45

US3202057

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:16:59
User entered 'VISIT4'	System	02 Mar 2021 21:38:45

US3202057

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:16:59
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	30 Mar 2021 19:55:02

US3202057

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:16:59
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Teresa Deese (b) (4)	30 Mar 2021 19:55:02

US3202057

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:16:59
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Teresa Deese (b) (4)	30 Mar 2021 19:55:02

US3202057

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:16:59
User entered empty.	System	30 Mar 2021 19:55:02

US3202057

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:16:59
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Teresa Deese (b) (4)	30 Mar 2021 19:55:02

US3202057

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:16:59
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Teresa Deese (b) (4)	30 Mar 2021 19:55:02

US3202057

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:16:59
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Teresa Deese (b) (4)	30 Mar 2021 19:55:02

US3202057

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:16:59
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Teresa Deese (b) (4)	30 Mar 2021 19:55:02

US3202057

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:16:59
User entered empty.	System	30 Mar 2021 19:55:02

US3202057

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:16:59
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Teresa Deese (b) (4)	30 Mar 2021 19:55:02

US3202057

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:16:59
User entered empty.	System	30 Mar 2021 19:55:02

US3202057

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:16:59
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Teresa Deese (b) (4)	30 Mar 2021 19:55:02

US3202057

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:16:59
User entered empty.	System	30 Mar 2021 19:55:02

US3202057

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:16:59
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Teresa Deese (b) (4)	30 Mar 2021 19:55:02

US3202057

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:16:59
User entered empty.	System	30 Mar 2021 19:55:02

US3202057

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:16:59

US3202057

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:16:59

US3202057

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:16:59
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	03 Mar 2021 17:43:22

US3202057

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:16:59
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Teresa Deese (b) (4)	03 Mar 2021 17:43:22

US3202057

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:16:59
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	03 Mar 2021 17:43:15

US3202057

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:16:59
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '2 Mar 2021'	(b) (4) Teresa Deese (b) (4)	03 Mar 2021 17:43:15

US3202057

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:16:59
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '14:35'	(b) (4) Teresa Deese (b) (4)	03 Mar 2021 17:43:15

US3202057

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:16:59
User entered '2 Mar 2021 14:35'	System	03 Mar 2021 17:43:15

US3202057

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:16:59
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	03 Mar 2021 17:42:58

US3202057

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:16:59
User entered '1'	System	03 Mar 2021 17:42:58

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:05:41

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '12 Sep 2020'	(b) (4) zackery harmon (b) (4)	24 Sep 2020 13:38:31
	(b) (4)	

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:05:41

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '11:00'	(b) (4) zackery harmon (b) (4)	24 Sep 2020 13:38:31
	(b) (4)	

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:05:41

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:03
User entered '12 Sep 2020 11:00'	System	24 Sep 2020 13:38:31

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:05:41

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Convalescent Tele-visit (Convalescent Tele-visit)'	(b) (4) zackery harmon (b) (4)	24 Sep 2020 13:38:31

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:05:41

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	24 Sep 2020 13:38:31
	(b) (4)	

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Day 1 (Day 1)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:41:09

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '9 Sep 2020'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:41:09

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:41:09

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered missing code ND - Not Done.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:41:09

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User entered '%'	System	11 Dec 2020 16:41:09

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered missing code ND - Not Done.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:41:09

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:41:09

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:41:09

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:41:09

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:41:09

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:41:09

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:41:09

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:41:09

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:41:09

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:41:09

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:41:09

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:41:09

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:41:09

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:41:09

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:41:09

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:41:09

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:41:09

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Day 2 (Day 2)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:42:47

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '10 Sep 2020'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:42:47

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:42:47

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered missing code ND - Not Done.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:42:47

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User entered '%'	System	11 Dec 2020 16:42:47

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '37.2' C	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:42:47

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:42:47

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:42:47

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:42:47

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:42:47

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:42:47

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:42:47

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:42:47

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:42:47

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:42:47

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:42:47

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:42:47

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:42:47

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:42:47

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:42:47

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:42:47

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:42:47

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Day 3 (Day 3)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:43:14

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '11 Sep 2020'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:43:14

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '1'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:43:14

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:43:14

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User entered empty.	System	11 Dec 2020 16:43:14

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:43:14

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:43:14

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:43:14

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:43:14

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:43:14

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:43:14

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:43:14

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:43:14

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:43:14

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:43:14

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:43:14

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:43:14

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:43:14

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:43:14

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:43:14

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:43:14

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:43:14

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Day 4 (Day 4)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:49:50

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '12 Sep 2020'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:49:50

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:49:50

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '98'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:49:50

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User entered '%'	System	11 Dec 2020 16:49:50

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '36.8' C	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:49:50

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:49:50

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:49:50

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:49:50

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:49:50

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:49:50

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:49:50

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:49:50

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:49:50

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:49:50

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:49:50

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:49:50

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:49:50

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:49:50

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:49:50

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:49:50

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 16:49:50

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:05:41

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '10 Sep 2020'	(b) (4) zackery harmon (b) (4)	19 Oct 2020 12:00:43
	(b) (4)	

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:05:41

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	19 Oct 2020 12:00:43
	(b) (4)	

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:05:41

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	19 Oct 2020 12:00:43
	(b) (4)	

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:05:41

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '10 Sep 2020'	(b) (4) zackery harmon (b) (4)	19 Oct 2020 12:00:43
	(b) (4)	

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:05:41

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Nasopharyngeal Swab (Nasopharyngeal zackery harmon Swab)'	(b) (4)	19 Oct 2020 12:00:43

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:05:41

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) zackery harmon (b) (4)	19 Oct 2020 12:00:43
	(b) (4)	

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:05:41

[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)	29 Apr 2021 00:24:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	19 Oct 2020 12:00:43
	(b) (4)	

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:05:41

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) zackery harmon (b) (4)	19 Oct 2020 12:00:43
	(b) (4)	

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:05:41

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) zackery harmon (b) (4)	19 Oct 2020 12:00:43
	(b) (4)	

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:05:41

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:29
User entered '0'	System	19 Oct 2020 12:00:43

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:05:41

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:24:57
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	11 Dec 2020 16:54:15
User entered 'No (N)' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	24 Sep 2020 13:38:46
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	24 Sep 2020 13:38:35

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:05:41

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:25:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '27 Oct 2020'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:02:36

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:05:41

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:25:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '16:00'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:02:36

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:05:41

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:25:29
User entered '27 Oct 2020 16:00'	System	11 Dec 2020 17:02:36

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:05:41

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:25:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Safety Call (Safety Call)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:02:36

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:05:41

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:25:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:02:36

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Day 1 (Day 1)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:03:54

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '24 Oct 2020'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:03:54

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:03:54

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered missing code ND - Not Done.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:03:54

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User entered '%'	System	11 Dec 2020 17:03:54

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered missing code ND - Not Done.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:03:54

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:03:54

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:03:54

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:03:54

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:03:54

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:03:54

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:03:54

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:03:54

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:03:54

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:03:54

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:03:54

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:03:54

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:03:54

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:03:54

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:03:54

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:03:54

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:03:54

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Day 2 (Day 2)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:10

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '25 Oct 2020'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:10

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:10

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered missing code ND - Not Done.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:10

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User entered '%'	System	11 Dec 2020 17:05:10

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '96.8' F	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:10

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:10

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:10

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:10

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:10

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:10

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:10

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:10

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:10

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:10

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:10

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:10

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:10

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:10

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:10

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:10

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:10

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Day 3 (Day 3)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:41

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '26 Oct 2020'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:41

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:41

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered missing code ND - Not Done.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:41

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User entered '%'	System	11 Dec 2020 17:05:41

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered missing code ND - Not Done.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:41

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:41

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:41

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:41

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:41

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:41

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:41

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:41

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:41

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:41

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:41

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:41

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:41

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:41

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:41

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:41

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:05:41

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Day 4 (Day 4)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:09:29

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '27 Oct 2020'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:09:29

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:09:29

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered missing code ND - Not Done.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:09:29

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User entered '%'	System	11 Dec 2020 17:09:29

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '101.0' F	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:09:29

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:09:29

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:09:29

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:09:29

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:09:29

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:09:29

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:09:29

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:09:29

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:09:29

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:09:29

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:09:29

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:09:29

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:09:29

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:09:29

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:09:29

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:09:29

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:09:29

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Day 5 (Day 5)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:23:53

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:28:17
User entered '28 Oct 2020' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	11 Dec 2020 17:37:55
User entered '29 Oct 2020'	Erica Osmundsen (b) (4)	11 Dec 2020 17:23:53

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:23:53

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:28:17
User entered missing code ND - Not Done; reason for change Data Entry Error	Erica Osmundsen (b) (4)	11 Dec 2020 17:37:55
User entered '97'	Erica Osmundsen (b) (4)	11 Dec 2020 17:23:53

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User entered '%'	System	11 Dec 2020 17:23:53

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '99.3' F reason for change: Data Entry Error	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:37:55
User entered '97.0' F	Erica Osmundsen (b) (4)	11 Dec 2020 17:23:53

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:37:55
User entered 'None (None)'	Erica Osmundsen (b) (4)	11 Dec 2020 17:23:53

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:23:53

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	11 Dec 2020 17:37:55
User entered 'Mild (Mild)'	Erica Osmundsen (b) (4)	11 Dec 2020 17:23:53

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:23:53

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:23:53

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	11 Dec 2020 17:37:55
User entered 'Mild (Mild)'	Erica Osmundsen (b) (4)	11 Dec 2020 17:23:53

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:23:53

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:23:53

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:23:53

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:23:53

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:23:53

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:23:53

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:23:53

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:23:53

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	11 Dec 2020 17:37:55
User entered 'Mild (Mild)'	Erica Osmundsen (b) (4)	11 Dec 2020 17:23:53

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	11 Dec 2020 17:37:55
User entered 'Mild (Mild)'	Erica Osmundsen (b) (4)	11 Dec 2020 17:23:53

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Day 6 (Day 6)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:39:26

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '29 Oct 2020'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:39:26

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:39:26

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '97'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:39:26

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User entered '%'	System	11 Dec 2020 17:39:26

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '97.0' F	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:39:26

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:39:26

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:39:26

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:39:26

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:39:26

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:39:26

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:39:26

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:39:26

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:39:26

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:39:26

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:39:26

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:39:26

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:39:26

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:39:26

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:39:26

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:39:26

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:39:26

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:05:41

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Day 7 (Day 7)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:16

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:05:41

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '30 Oct 2020'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:16

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '1'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:16

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:16

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User entered empty.	System	11 Dec 2020 17:40:16

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:05:41

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:16

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:05:41

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:16

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:05:41

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:16

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:05:41

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:16

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:05:41

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:16

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:05:41

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:16

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:05:41

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:16

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:05:41

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:16

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:05:41

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:16

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:16

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:16

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:05:41

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:16

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:16

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:16

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:16

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:05:41

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:16

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:16

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Day 8 (Day 8)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:37

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:05:41

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '31 Oct 2020'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:37

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'I'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:37

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:37

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User entered empty.	System	11 Dec 2020 17:40:37

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:37

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:05:41

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:37

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:37

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:05:41

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:37

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:05:41

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:37

US3202057

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:37

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:37

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:05:41

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:37

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:05:41

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:37

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:37

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:37

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:05:41

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:37

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:05:41

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:37

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:05:41

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:37

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:05:41

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:37

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:05:41

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:37

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:05:41

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:37

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Day 9 (Day 9)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:50

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '1 Nov 2020'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:50

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '1'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:50

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:50

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User entered empty.	System	11 Dec 2020 17:40:50

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:50

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:50

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:50

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:50

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:50

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:50

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:50

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:50

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:50

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:50

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:50

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:50

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:50

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:50

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:50

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:50

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:40:50

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Day 10 (Day 10)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:41:59

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '2 Nov 2020'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:41:59

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:41:59

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '97'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:41:59

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User entered '%'	System	11 Dec 2020 17:41:59

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '98.8' F	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:41:59

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:41:59

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:41:59

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:41:59

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:41:59

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:41:59

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:41:59

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:41:59

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:41:59

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:41:59

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:41:59

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:41:59

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:41:59

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:41:59

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:41:59

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:41:59

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:41:59

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:05:41

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '28 Oct 2020'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:42:28

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:05:41

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:42:28

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:05:41

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:42:28

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:05:41

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '28 Oct 2020'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:42:28

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:05:41

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:42:28

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:05:41

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:42:28

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:05:41

[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)	29 Apr 2021 00:26:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:42:28

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:05:41

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:42:28

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:05:41

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 17:42:28

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:05:41

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:26:12
User entered '0'	System	11 Dec 2020 17:42:28

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:05:41

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	zackery harmon (b) (4) (b) (4)	24 Sep 2020 13:21:41

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:05:41

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) zackery harmon (b) (4)	24 Sep 2020 13:21:41
	(b) (4)	

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:05:41

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	24 Sep 2020 13:21:41
	(b) (4)	

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:05:41

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	zackery harmon (b) (4) (b) (4)	24 Sep 2020 13:21:41

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:05:41

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) zackery harmon (b) (4)	24 Sep 2020 13:21:41
	(b) (4)	

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:05:41

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	24 Sep 2020 13:21:41
	(b) (4)	

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:05:41

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	zackery harmon (b) (4) (b) (4)	24 Sep 2020 13:21:41

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:05:41

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) zackery harmon (b) (4)	24 Sep 2020 13:21:41
	(b) (4)	

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:05:41

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	24 Sep 2020 13:21:41
	(b) (4)	

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:05:41

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	zackery harmon (b) (4) (b) (4)	24 Sep 2020 13:21:41

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:05:41

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) zackery harmon (b) (4)	24 Sep 2020 13:21:41
	(b) (4)	

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:05:41

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	24 Sep 2020 13:21:41
	(b) (4)	

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:05:41

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	zackery harmon (b) (4) (b) (4)	24 Sep 2020 13:21:41

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:05:41

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) zackery harmon (b) (4)	24 Sep 2020 13:21:41
	(b) (4)	

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:05:41

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	24 Sep 2020 13:21:41
	(b) (4)	

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:05:41

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	zackery harmon (b) (4) (b) (4)	24 Sep 2020 13:21:41

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:05:41

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) zackery harmon (b) (4)	24 Sep 2020 13:21:41
	(b) (4)	

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:05:41

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	24 Sep 2020 13:21:41
	(b) (4)	

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:05:41

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	zackery harmon (b) (4) (b) (4)	24 Sep 2020 13:21:41

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:05:41

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) zackery harmon (b) (4)	24 Sep 2020 13:21:41
	(b) (4)	

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:05:41

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	24 Sep 2020 13:21:41
	(b) (4)	

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:05:41

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Erica Osmundsen (b) (4)	18 Nov 2020 02:35:17
	[REDACTED]	
	[REDACTED]	

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:05:41

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
	(b) (4)	
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	18 Nov 2020 02:35:17

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:05:41

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02NOV2020 is recorded under Illness Visit Day 3 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Dec 2020 11:36:16
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02NOV2020 is recorded under Illness Visit Day 3 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'THE SAMPLE IS REPORTED IN GCL PORTAL FOR ACCESSION NUMBER 1F64086 COLLECTED ON 02NOV2020 RETURNED TO SITE ON 03NOV2020 AND THIS IS LISTED AS DRAW DATE IN LAB PORTAL' (Site from DM).	Erica Osmundsen (b) (4)	11 Dec 2020 17:45:44
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 03NOV2020 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)	08 Dec 2020 06:26:03
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02NOV2020 is recorded under Illness Visit Day 3 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 07:48:09

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:05:41

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 03NOV2020 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 'this is the day it was collected. ' (Site from DM).	zackery harmon (b) (4) (b) (4)	05 Dec 2020 13:11:57
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 03NOV2020 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 Dec 2020 04:09:38
User entered '2 Nov 2020'	Erica Osmundsen (b) (4)	18 Nov 2020 02:35:17

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:05:41

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Erica Osmundsen (b) (4)	18 Nov 2020 02:35:17
	[REDACTED]	
	[REDACTED]	

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:05:41

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Erica Osmundsen (b) (4)	18 Nov 2020 02:35:17

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:05:41

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	18 Nov 2020 02:35:17

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:05:41

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Erica Osmundsen (b) (4)	18 Nov 2020 02:35:17
	[REDACTED]	
	[REDACTED]	

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:05:41

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Erica Osmundsen (b) (4)	18 Nov 2020 02:35:17

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:05:41

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	18 Nov 2020 02:35:17
	(b) (4)	
	(b) (4)	

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:05:41

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Erica Osmundsen (b) (4)	18 Nov 2020 02:35:17
	[REDACTED]	
	[REDACTED]	

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:05:41

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Erica Osmundsen (b) (4)	18 Nov 2020 02:35:17
	(b) (4)	
	(b) (4)	

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:05:41

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	18 Nov 2020 02:35:17
	(b) (4)	
	(b) (4)	

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:05:41

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Erica Osmundsen (b) (4)	18 Nov 2020 02:35:17
	[REDACTED]	
	[REDACTED]	

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:05:41

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Erica Osmundsen (b) (4)	18 Nov 2020 02:35:17

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:05:41

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	18 Nov 2020 02:35:17

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:05:41

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Erica Osmundsen (b) (4)	18 Nov 2020 02:35:17
	[REDACTED]	
	[REDACTED]	

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:05:41

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Erica Osmundsen (b) (4)	18 Nov 2020 02:35:17
	(b) (4)	
	(b) (4)	

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:05:41

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	18 Nov 2020 02:35:17
	(b) (4)	
	(b) (4)	

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:05:41

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Erica Osmundsen (b) (4)	18 Nov 2020 02:35:17
	[REDACTED]	
	[REDACTED]	

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:05:41

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Erica Osmundsen (b) (4)	18 Nov 2020 02:35:17

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:05:41

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	18 Nov 2020 02:35:17
	(b) (4)	
	(b) (4)	

US3202057

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	24 Sep 2020 13:19:59
	(b) (4)	

US3202057

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '10 Sep 2020'	(b) (4) zackery harmon (b) (4)	24 Sep 2020 13:19:59
	(b) (4)	

US3202057

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Clinic (Clinic)'	(b) (4) zackery harmon (b) (4)	24 Sep 2020 13:19:59
	(b) (4)	

US3202057

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User entered 'SICKD1'	System	24 Sep 2020 13:19:59

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	24 Sep 2020 13:20:42
	(b) (4)	

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '10 Sep 2020'	(b) (4) zackery harmon (b) (4)	24 Sep 2020 13:20:42
	(b) (4)	

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '09:55'	(b) (4) zackery harmon (b) (4)	24 Sep 2020 13:20:42
	(b) (4)	

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User entered '10 Sep 2020 09:55'	System	24 Sep 2020 13:20:42

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '37.2' C	(b) (4) zackery harmon (b) (4)	24 Sep 2020 13:20:42
	(b) (4)	

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Oral (Oral)'	(b) (4) zackery harmon (b) (4)	24 Sep 2020 13:20:42
	(b) (4)	

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) zackery harmon (b) (4)	24 Sep 2020 13:20:42
	(b) (4)	

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '82'	(b) (4) zackery harmon (b) (4)	24 Sep 2020 13:20:42
	(b) (4)	

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User entered 'bpm'	System	24 Sep 2020 13:20:42

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '14'	(b) (4) zackery harmon (b) (4)	24 Sep 2020 13:20:42
	(b) (4)	

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User entered 'breaths/min'	System	24 Sep 2020 13:20:42

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '118'	(b) (4) zackery harmon (b) (4)	24 Sep 2020 13:20:42
	(b) (4)	

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User entered 'mmHg'	System	24 Sep 2020 13:20:42

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '74'	(b) (4) zackery harmon (b) (4)	24 Sep 2020 13:20:42
	(b) (4)	

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User entered 'mmHg'	System	24 Sep 2020 13:20:42

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47

US3202057

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	24 Sep 2020 13:20:52
	(b) (4)	

US3202057

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '10 Sep 2020'	(b) (4) zackery harmon (b) (4)	24 Sep 2020 13:20:52
	(b) (4)	

US3202057

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:05:41

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	24 Sep 2020 13:20:59
	(b) (4)	

US3202057

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:05:41

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '10 Sep 2020'	(b) (4) zackery harmon (b) (4)	24 Sep 2020 13:20:59
	(b) (4)	

US3202057

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02NOV2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 11:11:51
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02NOV2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit. Else clarify, thank you.' answered with 'entered saliva collection' (Site from DM).	Erica Osmundsen (b) (4)	18 Nov 2020 02:36:07
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02NOV2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 06:35:03
User entered 'Yes (Y)'	Teresa Deese (b) (4)	29 Oct 2020 19:51:33

US3202057

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '28 Oct 2020'	(b) (4) Teresa Deese (b) (4)	29 Oct 2020 19:51:33

US3202057

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Clinic (Clinic)'	(b) (4) Teresa Deese (b) (4)	29 Oct 2020 19:51:33

US3202057

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User entered 'SICKD1'	System	29 Oct 2020 19:51:33

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	29 Oct 2020 19:53:37

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '28 Oct 2020'	(b) (4) Teresa Deese (b) (4)	29 Oct 2020 19:53:37

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '15:05'	(b) (4) Teresa Deese (b) (4)	29 Oct 2020 19:53:37

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User entered '28 Oct 2020 15:05'	System	29 Oct 2020 19:53:37

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '37.4' C	(b) (4) Teresa Deese (b) (4)	29 Oct 2020 19:53:37

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Oral (Oral)'	(b) (4) Teresa Deese (b) (4)	29 Oct 2020 19:53:37

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Teresa Deese (b) (4)	29 Oct 2020 19:53:37

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '98'	(b) (4) Teresa Deese (b) (4)	29 Oct 2020 19:53:37

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User entered 'bpm'	System	29 Oct 2020 19:53:37

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '24'	(b) (4) Teresa Deese (b) (4)	29 Oct 2020 19:53:37

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User entered 'breaths/min'	System	29 Oct 2020 19:53:37

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '112'	(b) (4) Teresa Deese (b) (4)	29 Oct 2020 19:53:37

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User entered 'mmHg'	System	29 Oct 2020 19:53:37

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:13:47
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per investigator' (Site from System).	Erica Osmundsen (b) (4)	18 Nov 2020 02:17:28
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		29 Oct 2020 19:53:37
User entered '58'	Teresa Deese (b) (4)	29 Oct 2020 19:53:37

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User entered 'mmHg'	System	29 Oct 2020 19:53:37

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47

US3202057

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	29 Oct 2020 19:53:45

US3202057

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '28 Oct 2020'	(b) (4) Teresa Deese (b) (4)	29 Oct 2020 19:53:45

US3202057

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:05:41

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	29 Oct 2020 19:54:04

US3202057

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:05:41

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '28 Oct 2020'	(b) (4) Teresa Deese (b) (4)	29 Oct 2020 19:54:04

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
	(b) (4)	
User entered 'No (N)'	zackery harmon (b) (4)	24 Sep 2020 13:21:08
	(b) (4)	

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	24 Sep 2020 13:21:08
	(b) (4)	

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	24 Sep 2020 13:21:08
	(b) (4)	

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	24 Sep 2020 13:21:08

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
	(b) (4)	
User entered 'No (N)'	zackery harmon (b) (4)	24 Sep 2020 13:21:14
	(b) (4)	

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	24 Sep 2020 13:21:14
	(b) (4)	

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	24 Sep 2020 13:21:14
	(b) (4)	

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 13:21:14

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	24 Sep 2020 13:21:14
	(b) (4)	

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	24 Sep 2020 13:21:14
	(b) (4)	

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	24 Sep 2020 13:21:14
	(b) (4)	

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	24 Sep 2020 13:21:14
	(b) (4)	

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 13:21:14

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	24 Sep 2020 13:21:14
	(b) (4)	

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 13:21:14

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	24 Sep 2020 13:21:14
	(b) (4)	

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 13:21:14

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	24 Sep 2020 13:21:14
	(b) (4)	

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 13:21:14

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
	(b) (4)	
User entered 'No (N)'	zackery harmon (b) (4)	24 Sep 2020 13:21:18
	(b) (4)	

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	24 Sep 2020 13:21:18
	(b) (4)	

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:05:41

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) zackery harmon (b) (4)	24 Sep 2020 13:21:24
	(b) (4)	

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:05:41

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	24 Sep 2020 13:21:24
	(b) (4)	

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:31:06

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '5 Jan 2021'	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:31:06

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Clinic (Clinic)'	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:31:06

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered 'UNBLND_DECIDE'	System	05 Jan 2021 22:31:06

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:05:41

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '5 Jan 2021'	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:31:30

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:05:41

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered '0'	(b) (4) Teresa Deese (b) (4)	22 Apr 2021 15:07:15
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:25:21

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:05:41

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:31:30

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:05:41

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User closed query 'Per IRT system use and date: This subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Mark McKenzie (b) (4)	22 Apr 2021 18:34:32 22 Apr 2021 17:53:17
Query 'Per IRT system use and date: This subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'done' (Site from DM).	Teresa Deese (b) (4)	22 Apr 2021 15:07:31
User entered 'Amendment 6 or later (Amendment 6 or later)'	Teresa Deese (b) (4)	22 Apr 2021 15:07:15
User opened query 'Per IRT system use and date: This subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 07:39:25
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:25:21

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:05:41

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '5 Jan 2021'	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:31:30

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:05:41

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Placebo (Placebo)'	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:31:30

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:05:41

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 11:28:28
User entered 'Placebo (Placebo)'	Erica Osmundsen (b) (4)	05 Jan 2021 22:31:30

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:05:41

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 11:28:28
User entered 'Placebo (Placebo)'	Erica Osmundsen (b) (4)	05 Jan 2021 22:31:30

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:05:41

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:31:30

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:05:41

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered '1'	System	05 Jan 2021 22:31:30

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:05:41

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered '1'	System	05 Jan 2021 22:31:30

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:41

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '164.0' cm	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:40:45

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:41

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '66.4' kg	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:40:45

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:41

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered '24.68769'	System	05 Jan 2021 22:40:45
DataPoint set to visible.	System	05 Jan 2021 22:31:30

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:41

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '164.0' cm	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:40:45

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:41

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '66.4' kg	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:40:45

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:41

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered '24.68769'	System	05 Jan 2021 22:40:45
DataPoint set to visible.	System	05 Jan 2021 22:31:30

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User accepted default value 'Pre-Dose (PREDOSE)'	Erica Osmundsen (b) (4)	05 Jan 2021 22:40:45

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:40:45

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '05 Jan 2021'	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:40:45

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Jan 2021 22:43:56
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	05 Jan 2021 22:43:56
User entered '14:42' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	05 Jan 2021 22:43:56
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Jan 2021 22:40:45
User entered empty.	Erica Osmundsen (b) (4)	05 Jan 2021 22:40:45

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered '05 Jan 2021 14:42'	System	05 Jan 2021 22:43:56
User entered empty.	System	05 Jan 2021 22:40:45

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Jan 2021 22:43:56
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	05 Jan 2021 22:43:56
User entered '36.7' C reason for change: Data Entry Error	Erica Osmundsen (b) (4)	05 Jan 2021 22:43:56
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Jan 2021 22:40:45
User entered empty.	Erica Osmundsen (b) (4)	05 Jan 2021 22:40:45

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:28:17
User entered 'Oral (Oral)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	05 Jan 2021 22:43:56
User entered empty.	Erica Osmundsen (b) (4)	05 Jan 2021 22:40:45

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:40:45

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Jan 2021 22:43:56
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	05 Jan 2021 22:43:56
User entered '79' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	05 Jan 2021 22:43:56
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Jan 2021 22:40:45
User entered empty.	Erica Osmundsen (b) (4)	05 Jan 2021 22:40:45

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered 'bpm'	System	05 Jan 2021 22:43:56
User entered empty.	System	05 Jan 2021 22:40:45

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Jan 2021 22:43:56
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	05 Jan 2021 22:43:56
User entered '16' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	05 Jan 2021 22:43:56
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Jan 2021 22:40:45
User entered empty.	Erica Osmundsen (b) (4)	05 Jan 2021 22:40:45

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered 'breaths/min'	System	05 Jan 2021 22:43:56
User entered empty.	System	05 Jan 2021 22:40:45

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Jan 2021 22:43:56
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	05 Jan 2021 22:43:56
User entered '103' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	05 Jan 2021 22:43:56
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Jan 2021 22:40:45
User entered empty.	Erica Osmundsen (b) (4)	05 Jan 2021 22:40:45

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered 'mmHg'	System	05 Jan 2021 22:43:56
User entered empty.	System	05 Jan 2021 22:40:45

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Jan 2021 22:43:56
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	05 Jan 2021 22:43:56
User entered '64' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	05 Jan 2021 22:43:56
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Jan 2021 22:40:45
User entered empty.	Erica Osmundsen (b) (4)	05 Jan 2021 22:40:45

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered 'mmHg'	System	05 Jan 2021 22:43:56
User entered empty.	System	05 Jan 2021 22:40:45

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:41

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '164.0' cm	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:40:45

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:41

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '66.4' kg	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:40:45

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:41

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered '24.68769'	System	05 Jan 2021 22:40:45
DataPoint set to visible.	System	05 Jan 2021 22:31:30

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User accepted default value 'Post-Dose (POSTDOSE)'	Erica Osmundsen (b) (4)	05 Jan 2021 22:40:45

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:40:45

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '5 Jan 2021'	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:40:45

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Jan 2021 22:46:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	05 Jan 2021 22:46:05
User entered '17:29' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	05 Jan 2021 22:46:05
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Jan 2021 22:40:45
User entered empty.	Erica Osmundsen (b) (4)	05 Jan 2021 22:40:45

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered '5 Jan 2021 17:29'	System	05 Jan 2021 22:46:05
User entered empty.	System	05 Jan 2021 22:40:45

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Jan 2021 22:46:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	05 Jan 2021 22:46:05
User entered '97.9' F reason for change: Data Entry Error	Erica Osmundsen (b) (4)	05 Jan 2021 22:46:05
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Jan 2021 22:40:45
User entered empty.	Erica Osmundsen (b) (4)	05 Jan 2021 22:40:45

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Jan 2021 22:46:55
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	05 Jan 2021 22:46:55
User entered 'Oral (Oral)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	05 Jan 2021 22:46:55
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Jan 2021 22:46:05
User entered empty.	Erica Osmundsen (b) (4)	05 Jan 2021 22:40:45

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:40:45

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Jan 2021 22:46:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	05 Jan 2021 22:46:05
User entered '76' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	05 Jan 2021 22:46:05
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Jan 2021 22:40:45
User entered empty.	Erica Osmundsen (b) (4)	05 Jan 2021 22:40:45

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered 'bpm'	System	05 Jan 2021 22:46:05
User entered empty.	System	05 Jan 2021 22:40:45

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Jan 2021 22:46:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	05 Jan 2021 22:46:05
User entered '14' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	05 Jan 2021 22:46:05
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Jan 2021 22:40:45
User entered empty.	Erica Osmundsen (b) (4)	05 Jan 2021 22:40:45

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered 'breaths/min'	System	05 Jan 2021 22:46:05
User entered empty.	System	05 Jan 2021 22:40:45

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Jan 2021 22:46:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	05 Jan 2021 22:46:05
User entered '107' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	05 Jan 2021 22:46:05
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Jan 2021 22:40:45
User entered empty.	Erica Osmundsen (b) (4)	05 Jan 2021 22:40:45

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered 'mmHg'	System	05 Jan 2021 22:46:05
User entered empty.	System	05 Jan 2021 22:40:45

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Jan 2021 22:46:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	05 Jan 2021 22:46:05
User entered '65' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	05 Jan 2021 22:46:05
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Jan 2021 22:40:45
User entered empty.	Erica Osmundsen (b) (4)	05 Jan 2021 22:40:45

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered 'mmHg'	System	05 Jan 2021 22:46:05
User entered empty.	System	05 Jan 2021 22:40:45

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:47:21

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '5 Jan 2021'	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:47:21

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:47:34

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '5 Jan 2021'	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:47:34

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Urine (URINE)'	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:47:34

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Negative (NEGATIVE)'	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:47:34

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:47:34

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:47:34

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:47:34

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered empty.	System	05 Jan 2021 22:47:34

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:48:13

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:48:13

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

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)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:48:13

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered 'mRNA-1273'	System	05 Jan 2021 22:48:13
DataPoint set to visible.	System	05 Jan 2021 22:31:30

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '5 Jan 2021'	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:48:13

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '16:58'	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:48:13

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered '5 Jan 2021 16:58'	System	05 Jan 2021 22:48:13

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Left Arm (LEFT ARM)'	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:48:13

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered 'ONCE'	System	05 Jan 2021 22:48:13

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered 'INTRAMUSCULAR'	System	05 Jan 2021 22:48:13

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:50:36

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '5 Jan 2021'	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:50:36

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '16:56'	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:50:36

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered '5 Jan 2021 16:56'	System	05 Jan 2021 22:50:36

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:05:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:55:47

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:05:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '5 Jan 2021'	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:55:47

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:05:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '16:54'	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:55:47

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:05:41

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered '5 Jan 2021 16:54'	System	05 Jan 2021 22:55:47

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	05 Jan 2021 22:55:56

US3202057

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered '1'	System	05 Jan 2021 22:55:56

US3202057

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	15 Jan 2021 00:17:07

US3202057

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '14 Jan 2021'	(b) (4) Lilian Nukuna (b) (4)	15 Jan 2021 00:17:07

US3202057

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4)	15 Jan 2021 00:17:07

US3202057

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Lilian Nukuna (b) (4)	15 Jan 2021 00:17:07
	(b) (4)	

US3202057

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	Lilian Nukuna (b) (4)	15 Jan 2021 00:17:13

US3202057

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered '1'	System	15 Jan 2021 00:17:13

US3202057

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered '1'	System	15 Jan 2021 00:17:13
DataPoint set to visible.	System	15 Jan 2021 00:17:13

US3202057

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	02 Feb 2021 20:13:42

US3202057

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '2 Feb 2021'	(b) (4) Teresa Deese (b) (4)	02 Feb 2021 20:13:42

US3202057

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Clinic (Clinic)'	(b) (4) Teresa Deese (b) (4)	02 Feb 2021 20:13:42

US3202057

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered 'OLD29'	System	02 Feb 2021 20:13:42

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User accepted default value 'Pre-Dose (PREDOSE)'	Teresa Deese (b) (4)	02 Feb 2021 20:14:21

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	02 Feb 2021 20:14:21

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '2 Feb 2021'	(b) (4) Teresa Deese (b) (4)	02 Feb 2021 20:14:21

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '13:50'	(b) (4) Teresa Deese (b) (4)	02 Feb 2021 20:14:21

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered '2 Feb 2021 13:50'	System	02 Feb 2021 20:14:21

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '36.8' C	(b) (4) Teresa Deese (b) (4)	02 Feb 2021 20:14:21

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Oral (Oral)'	(b) (4) Teresa Deese (b) (4)	02 Feb 2021 20:14:21

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Teresa Deese (b) (4)	02 Feb 2021 20:14:21

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '76'	(b) (4) Teresa Deese (b) (4)	02 Feb 2021 20:14:21

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered 'bpm'	System	02 Feb 2021 20:14:21

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '16'	(b) (4) Teresa Deese (b) (4)	02 Feb 2021 20:14:21

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered 'breaths/min'	System	02 Feb 2021 20:14:21

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '104'	(b) (4) Teresa Deese (b) (4)	02 Feb 2021 20:14:21

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered 'mmHg'	System	02 Feb 2021 20:14:21

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '72'	(b) (4) Teresa Deese (b) (4)	02 Feb 2021 20:14:21

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered 'mmHg'	System	02 Feb 2021 20:14:21

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User accepted default value 'Post-Dose (POSTDOSE)'	Teresa Deese (b) (4)	02 Feb 2021 20:14:54

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	02 Feb 2021 20:14:54

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '2 Feb 2021'	(b) (4) Teresa Deese (b) (4)	02 Feb 2021 20:14:54

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '14:35'	(b) (4) Teresa Deese (b) (4)	02 Feb 2021 20:14:54

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered '2 Feb 2021 14:35'	System	02 Feb 2021 20:14:54

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '37' C	(b) (4) Teresa Deese (b) (4)	02 Feb 2021 20:14:54

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Oral (Oral)'	(b) (4) Teresa Deese (b) (4)	02 Feb 2021 20:14:54

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Teresa Deese (b) (4)	02 Feb 2021 20:14:54

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '78'	(b) (4) Teresa Deese (b) (4)	02 Feb 2021 20:14:54

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered 'bpm'	System	02 Feb 2021 20:14:54

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '15'	(b) (4) Teresa Deese (b) (4)	02 Feb 2021 20:14:54

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered 'breaths/min'	System	02 Feb 2021 20:14:54

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '105'	(b) (4) Teresa Deese (b) (4)	02 Feb 2021 20:14:54

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered 'mmHg'	System	02 Feb 2021 20:14:54

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '70'	(b) (4) Teresa Deese (b) (4)	02 Feb 2021 20:14:54

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered 'mmHg'	System	02 Feb 2021 20:14:54

US3202057

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	02 Feb 2021 20:14:59

US3202057

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Teresa Deese (b) (4)	02 Feb 2021 20:14:59

US3202057

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	02 Feb 2021 20:15:11

US3202057

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '2 Feb 2021'	(b) (4) Teresa Deese (b) (4)	02 Feb 2021 20:15:11

US3202057

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Urine (URINE)'	(b) (4) Teresa Deese (b) (4)	02 Feb 2021 20:15:11

US3202057

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Negative (NEGATIVE)'	(b) (4) Teresa Deese (b) (4)	02 Feb 2021 20:15:11

US3202057

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	02 Feb 2021 20:15:11

US3202057

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Teresa Deese (b) (4)	02 Feb 2021 20:15:11

US3202057

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Teresa Deese (b) (4)	02 Feb 2021 20:15:11

US3202057

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered empty.	System	02 Feb 2021 20:15:11

US3202057

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User closed query 'Per CDM: Open Label Day 29 date is not present in IRT. Please update IRT else clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 17:05:21
Query 'Per CDM: Open Label Day 29 date is not present in IRT. Please update IRT else clarify. ' answered with 'open label day 29 is registered in IRT for correct date and confirmed again this morning upon IRT login to the system' (Site from DM).	Erica Osmundsen (b) (4)	14 Apr 2021 13:22:35
User opened query 'Per CDM: Open Label Day 29 date is not present in IRT. Please update IRT else clarify. ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 09:00:09
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	02 Feb 2021 20:15:28

US3202057

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Teresa Deese (b) (4)	02 Feb 2021 20:15:28

US3202057

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

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)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Teresa Deese (b) (4)	02 Feb 2021 20:15:28

US3202057

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered 'mRNA-1273'	System	02 Feb 2021 20:15:28
DataPoint set to visible.	System	15 Jan 2021 00:17:13

US3202057

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '2 Feb 2021'	(b) (4) Teresa Deese (b) (4)	02 Feb 2021 20:15:28

US3202057

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '13:58'	(b) (4) Teresa Deese (b) (4)	02 Feb 2021 20:15:28

US3202057

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered '2 Feb 2021 13:58'	System	02 Feb 2021 20:15:28

US3202057

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Left Arm (LEFT ARM)'	(b) (4) Teresa Deese (b) (4)	02 Feb 2021 20:15:28

US3202057

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered 'ONCE'	System	02 Feb 2021 20:15:28

US3202057

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered 'INTRAMUSCULAR'	System	02 Feb 2021 20:15:28

US3202057

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	02 Feb 2021 20:15:32

US3202057

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered '1'	System	02 Feb 2021 20:15:32

US3202057

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	13 Feb 2021 23:17:11
	(b) (4)	

US3202057

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User closed query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 14:40:56
Query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'schedule conflict between site & subj' (Site from System).	Teresa Deese (b) (4)	18 Feb 2021 15:03:47
Amendment Manager: User opened query 'OL Safety System Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		17 Feb 2021 00:40:23
User entered '13 Feb 2021'	zackery harmon (b) (4) (b) (4)	13 Feb 2021 23:17:11

US3202057

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) zackery harmon (b) (4)	13 Feb 2021 23:17:11

US3202057

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) zackery harmon (b) (4)	13 Feb 2021 23:17:11
	(b) (4)	

US3202057

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	13 Feb 2021 23:17:16
	(b) (4)	

US3202057

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered '1'	System	13 Feb 2021 23:17:16

US3202057

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	Lilian Nukuna (b) (4)	02 Mar 2021 21:39:02

US3202057

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '2 Mar 2021'	Lilian Nukuna (b) (4)	02 Mar 2021 21:39:02

US3202057

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Clinic (Clinic)'	Lilian Nukuna (b) (4)	02 Mar 2021 21:39:02

US3202057

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered 'OLD57'	System	02 Mar 2021 21:39:02

US3202057

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	13 Mar 2021 15:47:14
	(b) (4)	

US3202057

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) zackery harmon (b) (4)	13 Mar 2021 15:47:14

US3202057

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) zackery harmon (b) (4)	13 Mar 2021 15:47:14

US3202057

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered empty.	System	13 Mar 2021 15:47:14

US3202057

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) zackery harmon (b) (4)	13 Mar 2021 15:47:14
	(b) (4)	

US3202057

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) zackery harmon (b) (4)	13 Mar 2021 15:47:14

US3202057

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) zackery harmon (b) (4)	13 Mar 2021 15:47:14
	(b) (4)	

US3202057

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) zackery harmon (b) (4)	13 Mar 2021 15:47:14

US3202057

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered empty.	System	13 Mar 2021 15:47:14

US3202057

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) zackery harmon (b) (4)	13 Mar 2021 15:47:14
	(b) (4)	

US3202057

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered empty.	System	13 Mar 2021 15:47:14

US3202057

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) zackery harmon (b) (4)	13 Mar 2021 15:47:14

US3202057

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered empty.	System	13 Mar 2021 15:47:14

US3202057

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) zackery harmon (b) (4)	13 Mar 2021 15:47:14

US3202057

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered empty.	System	13 Mar 2021 15:47:14

US3202057

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42

US3202057

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42

US3202057

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'No (N)'	(b) (4) Lilian Nukuna (b) (4)	02 Mar 2021 21:40:04

US3202057

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered empty.	(b) (4) Lilian Nukuna (b) (4)	02 Mar 2021 21:40:04

US3202057

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	02 Mar 2021 21:40:53

US3202057

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User closed query 'Per GCL Lab Recon:LB4 Immuno: Requery: Per response "kits sent at that time were for vs 2&3 so no DCF needed" however there is still mismatch between visits in both database. Please verify and update else clarify in response.Thanks' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:21:04
Query 'Per GCL Lab Recon:LB4 Immuno: Requery: Per response "kits sent at that time were for vs 2&3 so no DCF needed" however there is still mismatch between visits in both database. Please verify and update else clarify in response.Thanks' answered with 'being updated in preclarus' (Site from DM).	Teresa Deese (b) (4)	16 Mar 2021 16:50:57
User opened query 'Per GCL Lab Recon:LB4 Immuno: Requery: Per response "kits sent at that time were for vs 2&3 so no DCF needed" however there is still mismatch between visits in both database. Please verify and update else clarify in response.Thanks' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 06:24:27
User closed query 'Per GCL Lab Recon:LB4 Immuno: Sample dated 02 MAR 2021 is recorded under the OL-D57 visit in EDC, however the same is reported under in OL-2 visit in PPD GCL. Please reconcile and confirm the correct Visit and update in EDC or Preclarus as necessary by sending a DCF if applicable. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 06:24:27
Query 'Per GCL Lab Recon:LB4 Immuno: Sample dated 02 MAR 2021 is recorded under the OL-D57 visit in EDC, however the same is reported under in OL-2 visit in PPD GCL. Please reconcile and confirm the correct Visit and update in EDC or Preclarus as necessary by sending a DCF if applicable. Thank you. ' answered with 'kits sent at that time were for vs 2&3 so no DCF needed' (Site from DM).	Teresa Deese (b) (4)	15 Mar 2021 14:44:08

US3202057

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Recon:LB4 Immuno: Sample dated 02 MAR 2021 is recorded under the OL-D57 visit in EDC, however the same is reported under in OL-2 visit in PPD GCL. Please reconcile and confirm the correct Visit and update in EDC or Preclarus as necessary by sending a DCF if applicable. Thank you. ' (Site from DM). User entered '2 Mar 2021'	(b) (4), (b) (6)	15 Mar 2021 11:14:17
	Lilian Nukuna (b) (4)	02 Mar 2021 21:40:53
	(b) (4)	

US3202057

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:17
User entered '14:35'	(b) (4) Lilian Nukuna (b) (4)	02 Mar 2021 21:40:53

US3202057

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:18:42
User entered '2 Mar 2021 14:35'	System	02 Mar 2021 21:40:53

US3202057

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:05:41

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:26:05
User closed query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 1 diary, FATIGUE lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 09:11:23
User closed query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 1 diary, MUSCLE ACHES lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 09:11:17
User closed query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 1 diary, HEADACHE lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 09:10:53
Query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 1 diary, MUSCLE ACHES lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' answered with 'updated' (Site from DM).	zackery harmon (b) (4) (b) (4)	19 Apr 2021 18:53:33

US3202057

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:05:41

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 1 diary, HEADACHE lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' answered with 'updated' (Site from DM).	zackery harmon (b) (4) (b) (4)	19 Apr 2021 18:53:14
Query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 1 diary, FATIGUE lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' answered with 'updated' (Site from DM).	zackery harmon (b) (4) (b) (4)	19 Apr 2021 18:52:55
User opened query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 1 diary, MUSCLE ACHES lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 04:59:30
User opened query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 1 diary, HEADACHE lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 04:59:25

US3202057

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:05:41

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 1 diary, FATIGUE lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) [REDACTED]	18 Apr 2021 04:59:18
	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:02:44
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6) [REDACTED]	16 Sep 2020 15:45:38
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 19:29:35

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[AEID](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	zackery harmon (b) (4) (b) (4)	19 Apr 2021 18:49:00
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4) (b) (4)	14 Oct 2020 21:16:07

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User closed query 'Per DM CLR: Please review this solicited event and please note, this is already captured on the subject's Diary record and it does not appear to meet any SAR reporting criteria. Please update to remove from the AE eCRF as applicable. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Apr 2021 09:10:38
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 18:50:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 18:50:32
Data point term sent to Coder	System	19 Apr 2021 18:49:51
Query 'Per DM CLR: Please review this solicited event and please note, this is already captured on the subject's Diary record and it does not appear to meet any SAR reporting criteria. Please update to remove from the AE eCRF as applicable. Otherwise, clarify.' answered with 'updated' (Site from DM).	zackery harmon (b) (4) (b) (4)	19 Apr 2021 18:49:36
DataPoint activated with code reason code Data required.	zackery harmon (b) (4) (b) (4)	19 Apr 2021 18:49:00
Data point term sent to Coder	System	14 Oct 2020 21:16:30
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4) (b) (4)	14 Oct 2020 21:16:07
User opened query 'Per DM CLR: Please review this solicited event and please note, this is already captured on the subject's Diary record and it does not appear to meet any SAR reporting criteria. Please update to remove from the AE eCRF as applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	11 Oct 2020 12:21:44
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 15:48:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 15:48:46
Data point term sent to Coder	System	16 Sep 2020 15:47:41
User entered 'headache'	(b) (4), (b) (6)	16 Sep 2020 15:47:14

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
	(b) (4)	
DataPoint activated with code reason code Data required.	zackery harmon (b) (4)	19 Apr 2021 18:49:00
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4)	14 Oct 2020 21:16:07
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	16 Sep 2020 15:47:14

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
	(b) (4)	
DataPoint activated with code reason code Data required.	zackery harmon (b) (4)	19 Apr 2021 18:49:00
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4)	14 Oct 2020 21:16:07
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 15:47:14

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
	(b) (4)	
DataPoint activated with code reason code Data required.	zackery harmon (b) (4)	19 Apr 2021 18:49:00
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4)	14 Oct 2020 21:16:07
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	16 Sep 2020 15:47:14

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
	(b) (4)	
User entered '07 Aug 2020' reason for change: Data Entry Error	zackery harmon (b) (4)	19 Apr 2021 18:49:30
	(b) (4)	
DataPoint activated with code reason code Data required.	zackery harmon (b) (4)	19 Apr 2021 18:49:00
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4)	14 Oct 2020 21:16:07
	(b) (4)	
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	16 Sep 2020 23:47:46
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	16 Sep 2020 15:47:14
User entered '13 Aug 2020'	(b) (4), (b) (6)	16 Sep 2020 15:47:14

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Apr 2021 18:49:59
User entered '16:00' reason for change: Data Entry Error	zackery harmon (b) (4)	19 Apr 2021 18:49:59
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Apr 2021 18:49:30
DataPoint activated with code reason code Data required.	zackery harmon (b) (4)	19 Apr 2021 18:49:00
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4)	14 Oct 2020 21:16:07
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 15:47:14

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 16:00'	System	19 Apr 2021 18:49:59
DataPoint activated with code reason code Data required.	zackery harmon (b) (4) (b) (4)	19 Apr 2021 18:49:00
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4) (b) (4)	14 Oct 2020 21:16:07
User entered empty.	System	16 Sep 2020 15:47:14

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
	(b) (4)	
DataPoint activated with code reason code Data required.	zackery harmon (b) (4)	19 Apr 2021 18:49:00
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4)	14 Oct 2020 21:16:07
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	16 Sep 2020 15:47:14

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
	(b) (4)	
User entered '14 Aug 2020' reason for change: Data Entry Error	zackery harmon (b) (4)	19 Apr 2021 18:49:30
	(b) (4)	
DataPoint activated with code reason code Data required.	zackery harmon (b) (4)	19 Apr 2021 18:49:00
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4)	14 Oct 2020 21:16:07
	(b) (4)	
User entered '13 Aug 2020'	(b) (4), (b) (6)	16 Sep 2020 15:47:14

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Apr 2021 18:49:59
User entered '08:00' reason for change: Data Entry Error	zackery harmon (b) (4)	19 Apr 2021 18:49:59
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Apr 2021 18:49:30
DataPoint activated with code reason code Data required.	zackery harmon (b) (4)	19 Apr 2021 18:49:00
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4)	14 Oct 2020 21:16:07
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 15:47:14

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 08:00'	System	19 Apr 2021 18:49:59
DataPoint activated with code reason code Data required.	zackery harmon (b) (4) (b) (4)	19 Apr 2021 18:49:00
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4) (b) (4)	14 Oct 2020 21:16:07
User entered empty.	System	16 Sep 2020 15:47:14

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
	(b) (4)	
DataPoint activated with code reason code Data required.	zackery harmon (b) (4)	19 Apr 2021 18:49:00
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4)	14 Oct 2020 21:16:07
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	16 Sep 2020 15:47:14

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
	(b) (4)	
DataPoint activated with code reason code Data required.	zackery harmon (b) (4)	19 Apr 2021 18:49:00
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4)	14 Oct 2020 21:16:07
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	16 Sep 2020 15:47:14

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
	(b) (4)	
DataPoint activated with code reason code Data required.	zackery harmon (b) (4)	19 Apr 2021 18:49:00
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4)	14 Oct 2020 21:16:07
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 15:47:14

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
	(b) (4)	
DataPoint activated with code reason code Data required.	zackery harmon (b) (4)	19 Apr 2021 18:49:00
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4)	14 Oct 2020 21:16:07
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 15:47:14

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
	(b) (4)	
DataPoint activated with code reason code Data required.	zackery harmon (b) (4)	19 Apr 2021 18:49:00
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4)	14 Oct 2020 21:16:07
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 15:47:14

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
	(b) (4)	
DataPoint activated with code reason code Data required.	zackery harmon (b) (4)	19 Apr 2021 18:49:00
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4)	14 Oct 2020 21:16:07
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 15:47:14

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
	(b) (4)	
DataPoint activated with code reason code Data required.	zackery harmon (b) (4)	19 Apr 2021 18:49:00
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4)	14 Oct 2020 21:16:07
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 15:47:14

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
	(b) (4)	
DataPoint activated with code reason code Data required.	zackery harmon (b) (4)	19 Apr 2021 18:49:00
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4)	14 Oct 2020 21:16:07
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 15:47:14

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
	(b) (4)	
DataPoint activated with code reason code Data required.	zackery harmon (b) (4)	19 Apr 2021 18:49:00
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4)	14 Oct 2020 21:16:07
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 15:47:14

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
	(b) (4)	
DataPoint activated with code reason code Data required.	zackery harmon (b) (4)	19 Apr 2021 18:49:00
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4)	14 Oct 2020 21:16:07
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 15:47:14

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
	(b) (4)	
DataPoint activated with code reason code Data required.	zackery harmon (b) (4)	19 Apr 2021 18:49:00
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4)	14 Oct 2020 21:16:07
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 15:47:14

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
	(b) (4)	
DataPoint activated with code reason code Data required.	zackery harmon (b) (4)	19 Apr 2021 18:49:00
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4)	14 Oct 2020 21:16:07
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 15:47:14

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
	(b) (4)	
User entered 'Related (RELATED)' reason for change: Data Entry Error	zackery harmon (b) (4)	19 Apr 2021 18:49:30
	(b) (4)	
DataPoint activated with code reason code Data required.	zackery harmon (b) (4)	19 Apr 2021 18:49:00
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4)	14 Oct 2020 21:16:07
	(b) (4)	
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 15:49:48
User entered 'Related (RELATED)'	(b) (4), (b) (6)	16 Sep 2020 15:47:14

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
	(b) (4)	
DataPoint activated with code reason code Data required.	zackery harmon (b) (4)	19 Apr 2021 18:49:00
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4)	14 Oct 2020 21:16:07
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Sep 2020 15:47:14

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
DataPoint activated with code reason code Data required.	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:49:00
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4)	14 Oct 2020 21:16:07
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 15:48:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 15:48:11
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 15:48:11
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 15:47:14
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 15:47:14

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

None

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
	(b) (4)	
DataPoint activated with code reason code Data required.	zackery harmon (b) (4)	19 Apr 2021 18:49:00
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4)	14 Oct 2020 21:16:07
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 15:47:14

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
	(b) (4)	
DataPoint activated with code reason code Data required.	zackery harmon (b) (4)	19 Apr 2021 18:49:00
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4)	14 Oct 2020 21:16:07
	(b) (4)	
User entered '1'	(b) (4), (b) (6)	16 Sep 2020 15:47:14

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
	(b) (4)	
DataPoint activated with code reason code Data required.	zackery harmon (b) (4)	19 Apr 2021 18:49:00
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4)	14 Oct 2020 21:16:07
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 15:47:14

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
	(b) (4)	
DataPoint activated with code reason code Data required.	zackery harmon (b) (4)	19 Apr 2021 18:49:00
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4)	14 Oct 2020 21:16:07
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	16 Sep 2020 15:47:14

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
	(b) (4)	
DataPoint activated with code reason code Data required.	zackery harmon (b) (4)	19 Apr 2021 18:49:00
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4)	14 Oct 2020 21:16:07
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 15:47:14

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
	(b) (4)	
DataPoint activated with code reason code Data required.	zackery harmon (b) (4)	19 Apr 2021 18:49:00
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4)	14 Oct 2020 21:16:07
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 15:47:14

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	zackery harmon (b) (4) (b) (4)	19 Apr 2021 18:49:00
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4) (b) (4)	14 Oct 2020 21:16:07
User entered '0'	System	16 Sep 2020 15:47:14

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	zackery harmon (b) (4) (b) (4)	19 Apr 2021 18:49:00
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4) (b) (4)	14 Oct 2020 21:16:07
User entered '0'	System	16 Sep 2020 15:47:14

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	zackery harmon (b) (4) (b) (4)	19 Apr 2021 18:49:00
DataPoint inactivated with code reason code Data not required.	Tiffany Jewell (b) (4) (b) (4)	14 Oct 2020 21:16:07

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:52

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:12:14
User closed query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 20:39:22
Query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' answered with 'NOT COVID-19--ILLNESS VISIT COMPLETED AND RESULT NEGATIVE' (Site from DM).	Erica Osmundsen (b) (4)	16 Dec 2020 22:04:22
User opened query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 22:34:10
User closed query 'Per DM CLR: Please review and update AE term to reflect specific body location and/or type of VIRAL INFECTION. Please reconcile with the ConMed eCRF so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 14:27:06
User coded data point as SOC: Infections and infestations, HLG: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 22:05:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 22:05:48
Data point term sent to Coder	System	18 Nov 2020 22:00:31
User entered 'UPPER RESPIRATORY INFECTION (UNKNOWN ETIOLOGY)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	18 Nov 2020 21:59:36
Query 'Per DM CLR: Please review and update AE term to reflect specific body location and/or type of VIRAL INFECTION. Please reconcile with the ConMed eCRF so there is an appropriate match.' answered with 'UPDATED PER SOURCE' (Site from DM).	Erica Osmundsen (b) (4)	18 Nov 2020 21:58:08
Data point term sent to Coder	System	18 Nov 2020 21:57:28
Coding entries removed.	Erica Osmundsen (b) (4)	18 Nov 2020 21:56:30

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'UPPER RESPIRATORY INFECTION UNKNOWN ETIOLOGY' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	18 Nov 2020 21:56:30
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral infection, LLT: Viral infection - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 17:28:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 17:28:37
User closed query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential covid-19 infection' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 15:49:35
User opened query 'Per DM CLR: Please review and update AE term to reflect specific body location and/or type of VIRAL INFECTION. Please reconcile with the ConMed eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 06:04:11
Query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential covid-19 infection' answered with 'pt was tested for covid 19 on sep 12th 2020' (Site from DM).	zackery harmon (b) (4)	19 Oct 2020 19:59:23
User opened query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential covid-19 infection' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 12:34:20
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral infection, LLT: Viral infection - version MedDRA\23.0.	Coder Import (b) (4)	16 Sep 2020 16:32:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	16 Sep 2020 16:32:40
Data point term sent to Coder	System	16 Sep 2020 16:31:06
User entered 'viral infection'	(b) (4), (b) (6)	16 Sep 2020 16:30:53

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:12:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:30:53

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:12:14
User closed query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, Viarl Infection is not one of the solicited events for this study. Please review and update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:49:26
Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, Viarl Infection is not one of the solicited events for this study. Please review and update accordingly. Otherwise, clarify.' answered with 'Field updated' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	14 Oct 2020 21:15:32
User entered 'No (N)' reason for change: Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	14 Oct 2020 21:15:23
User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, Viarl Infection is not one of the solicited events for this study. Please review and update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	11 Oct 2020 12:22:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 16:30:53

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:12:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:30:53

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:12:14
User entered '09 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:30:53

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:12:14
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:30:53

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:52
User entered empty.	System	16 Sep 2020 16:30:53

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:12:14
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:25:50
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'updated' (Site from DM).	zackery harmon (b) (4) (b) (4)	02 Dec 2020 17:41:25
User entered 'No (N)' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	02 Dec 2020 17:41:01
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 06:45:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 16:30:53

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:12:14
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4) System	02 Dec 2020 17:41:19
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	02 Dec 2020 17:41:19
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	02 Dec 2020 17:41:01
User entered '14 Sep 2020' reason for change: Data Entry Error	zackery harmon (b) (4)	02 Dec 2020 17:41:01
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:30:53

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:12:14
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:30:53

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:52
User entered empty.	System	16 Sep 2020 16:30:53

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:12:14
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:30:53

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:12:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:30:53

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:12:14
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:30:53

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:12:14
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:30:53

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:12:14
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:30:53

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:12:14
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:30:53

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:12:14
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:30:53

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:12:14
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:30:53

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:12:14
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:30:53

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:12:14
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:30:53

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:12:14
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:30:53

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:12:14
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:30:53

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:12:14
User entered 'Related (RELATED)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:30:53

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:12:14
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:30:53

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:12:14
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	16 Sep 2020 16:31:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 16:31:03
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 16:31:03
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 16:30:53
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 16:30:53

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:12:14
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:30:53

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:12:14
User entered '1'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:30:53

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:12:14
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:30:53

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:52
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:12:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	02 Dec 2020 17:41:19
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	16 Sep 2020 16:30:53

US3202057

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)	29 Apr 2021 12:01:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:12:14
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:30:53

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:12:14
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:30:53

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:52
User entered '0'	System	16 Sep 2020 16:30:53

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:52
User entered '0'	System	16 Sep 2020 16:30:53

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:52

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:58

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 18:51:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 18:51:36
Data point term sent to Coder	System	19 Apr 2021 18:50:55
User entered 'Fatigue'	zackery harmon (b) (4)	19 Apr 2021 18:50:37

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:50:37
	(b) (4)	

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:50:37
	(b) (4)	

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:50:37
	(b) (4)	

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered '08 Aug 2020'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:50:37
	(b) (4)	

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	19 Apr 2021 18:51:04
User entered '13:00' reason for change: Data Entry Error	zackery harmon (b) (4)	19 Apr 2021 18:51:04
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	19 Apr 2021 18:50:37
User entered empty.	zackery harmon (b) (4)	19 Apr 2021 18:50:37

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:58
User entered '08 Aug 2020 13:00'	System	19 Apr 2021 18:51:04
User entered empty.	System	19 Apr 2021 18:50:37

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:50:37
	(b) (4)	

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered '14 Aug 2020'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:50:37
	(b) (4)	

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	19 Apr 2021 18:51:04
User entered '08:00' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	19 Apr 2021 18:51:04
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Apr 2021 18:50:37
User entered empty.	zackery harmon (b) (4) (b) (4)	19 Apr 2021 18:50:37

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:58
User entered '14 Aug 2020 08:00'	System	19 Apr 2021 18:51:04
User entered empty.	System	19 Apr 2021 18:50:37

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:50:37
	(b) (4)	

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:50:37
	(b) (4)	

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered '0'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:50:37
	(b) (4)	

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered '0'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:50:37

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered '0'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:50:37
	(b) (4)	

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered empty.	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:50:37
	(b) (4)	

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered empty.	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:50:37
	(b) (4)	

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered empty.	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:50:37
	(b) (4)	

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered empty.	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:50:37
	(b) (4)	

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered '0'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:50:37

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered '0'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:50:37
	(b) (4)	

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered '0'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:50:37

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered 'Related (RELATED)'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:50:37
	(b) (4)	

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered 'Not Related (NOT RELATED)'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:50:37
	(b) (4)	

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered 'None (NONE)'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:50:37
	(b) (4)	

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered '1'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:50:37

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered '0'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:50:37

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered '0'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:50:37
	(b) (4)	

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:50:37

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered empty.	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:50:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered empty.	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:50:37
	(b) (4)	

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:58
User entered '0'	System	19 Apr 2021 18:50:37

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:58
User entered '0'	System	19 Apr 2021 18:50:37

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:58

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:02

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:02
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User closed query 'Per CDM: Please specify location of MUSCLE ACHES and ensure that there is a corresponding CM record that reconciles with this provided event if applicable, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:34:05
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Myalgia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 18:57:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 18:57:37
Data point term sent to Coder	System	20 Apr 2021 18:56:11
Coding entries removed.	Erica Osmundsen (b) (4)	20 Apr 2021 18:55:30
User entered 'MYALGIA (MUSCLE ACHES)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	20 Apr 2021 18:55:30
Query 'Per CDM: Please specify location of MUSCLE ACHES and ensure that there is a corresponding CM record that reconciles with this provided event if applicable, else clarify.' answered with 'THIS WAS DIRECT QUOTE FROM E-DIARY SOLICITED REACTION--GENERALIZED MUSCLE ACHES AND NO CONCOMITANT MEDICATION AS INDICATED ON THIS PAGE' (Site from DM).	Erica Osmundsen (b) (4)	20 Apr 2021 18:53:09
User opened query 'Per CDM: Please specify location of MUSCLE ACHES and ensure that there is a corresponding CM record that reconciles with this provided event if applicable, else clarify.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 17:38:08
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle ache - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 18:52:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 18:52:39

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Adverse event](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	19 Apr 2021 18:51:56
User entered 'Muscle aches'	zackery harmon (b) (4)	19 Apr 2021 18:51:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:02
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:51:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:02
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:51:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:02
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:51:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:02
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered '11 Aug 2020'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:51:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:02
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered empty.	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:51:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:02
User entered empty.	System	19 Apr 2021 18:51:50

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:02
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:51:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:02
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered '14 Aug 2020'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:51:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:02
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered empty.	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:51:50
	(b) (4)	

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:02
User entered empty.	System	19 Apr 2021 18:51:50

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:02
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:51:50
	(b) (4)	

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:02
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:51:50
	(b) (4)	

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:02
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered '0'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:51:50
	(b) (4)	

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:02
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered '0'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:51:50

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:02
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered '0'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:51:50

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:02
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered empty.	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:51:50
	(b) (4)	

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:02
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered empty.	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:51:50
	(b) (4)	

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:02
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered empty.	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:51:50
	(b) (4)	

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:02
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered empty.	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:51:50
	(b) (4)	

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:02
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered '0'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:51:50
	(b) (4)	

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:02
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered '0'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:51:50
	(b) (4)	

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:02
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered '0'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:51:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:02
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered 'Related (RELATED)'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:51:50
	(b) (4)	

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:02
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered 'Not Related (NOT RELATED)'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:51:50
	(b) (4)	

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:02
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered 'None (NONE)'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:51:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:02
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered '1'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:51:50

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:02
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered '0'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:51:50

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:02
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered '0'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:51:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:02
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:51:50

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:02
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered empty.	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:51:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:02
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:53:17
User entered empty.	(b) (4) zackery harmon (b) (4)	19 Apr 2021 18:51:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:02
User entered '0'	System	19 Apr 2021 18:51:50

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:02
User entered '0'	System	19 Apr 2021 18:51:50

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:02

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:05:41

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:26:05
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User closed query 'Per CDM: Per Diary Dose 2 Day 6 to 7,Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM). Query 'Per CDM: Per Diary Dose 2 Day 6 to 7,Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:36:30
Query 'Per CDM: Per Diary Dose 2 Day 6 to 7,Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'CONMEDS WERE UPDATED 12AUG2020 AND 09SEPT2020' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 14:23:47
User opened query 'Per CDM: Per Diary Dose 2 Day 6 to 7,Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 11:48:18
Query 'Per CDM: Per Diary Dose 1 Day 6 and Dose 2 Day 6 to 7,Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' canceled (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 11:48:01

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:05:41

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Per Diary Dose 1 Day 6 and Dose 2 Day 6 to 7,Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 11:46:30
Query 'Per DM CLR: Per Diary Dose 2 Day 6 to 7,Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' canceled (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 11:46:16
User opened query 'Per DM CLR: Per Diary Dose 2 Day 6 to 7,Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 11:46:13
User closed query 'Per DM CLR: Per Diary Dose 1 Day 6 and Dose 2 Day 6 to 7,Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 11:45:09

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:05:41

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Query 'Per DM CLR: Per Diary Dose 1 Day 6 and Dose 2 Day 6 to 7,Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 21:14:15
User opened query 'Per DM CLR: Per Diary Dose 1 Day 6 and Dose 2 Day 6 to 7,Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 05:33:57
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	19 Aug 2020 13:43:30

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:08:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Aug 2020 13:47:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Aug 2020 13:47:18
Data point term sent to Coder User entered 'ibuprofen'	System Lilian Nukuna (b) (4)	19 Aug 2020 13:46:25 19 Aug 2020 13:45:38

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:08:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User closed query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding record on the Diary Card that matches this ConMed. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:54:26
Query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding record on the Diary Card that matches this ConMed. If yes, please update eCRF as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 15:43:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 15:43:16
User opened query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding record on the Diary Card that matches this ConMed. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 10:31:05
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	19 Aug 2020 13:45:38

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:08:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Oct 2020 13:10:05
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 15:43:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:41

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 10:30:41
User entered 'headache'	Lilian Nukuna (b) (4) (b) (4)	19 Aug 2020 13:45:38

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:08:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered '800'	(b) (4) Lilian Nukuna (b) (4)	19 Aug 2020 13:45:38
	(b) (4)	

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:08:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered 'mg (mg)'	(b) (4) Lilian Nukuna (b) (4)	19 Aug 2020 13:45:38
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:08:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered empty.	(b) (4) Lilian Nukuna (b) (4)	19 Aug 2020 13:45:38
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:08:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered 'once daily (QD)'	(b) (4) Lilian Nukuna (b) (4)	19 Aug 2020 13:45:38
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:08:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered empty.	(b) (4) Lilian Nukuna (b) (4)	19 Aug 2020 13:45:38
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:08:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered 'Oral (ORAL)'	(b) (4) Lilian Nukuna (b) (4)	19 Aug 2020 13:45:38
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:08:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered empty.	(b) (4) Lilian Nukuna (b) (4)	19 Aug 2020 13:45:38
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:08:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered '13 Aug 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:44:37
User entered '12 Aug 2020'	Lilian Nukuna (b) (4) (b) (4)	19 Aug 2020 13:45:38

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:08:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered '0'	Lilian Nukuna (b) (4)	19 Aug 2020 13:45:38

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:08:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered 'No (N)'	(b) (4) Lilian Nukuna (b) (4)	19 Aug 2020 13:45:38
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:08:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered '13 Aug 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:44:37
User entered '12 Aug 2020'	Lilian Nukuna (b) (4) (b) (4)	19 Aug 2020 13:45:38

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:08:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	19 Aug 2020 13:45:38
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:08:19
User entered '1'	System	19 Aug 2020 13:45:38

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:08:19
User entered '1'	System	19 Aug 2020 13:45:38

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:08:19
User entered '804 (804)'	System	19 Aug 2020 13:45:38

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:41

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: FLUOXETINE HYDROCHLORIDE, PRODUCTSYNONYM: PROZAC - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	16 Sep 2020 16:39:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Sep 2020 16:39:49
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	16 Sep 2020 16:38:28 16 Sep 2020 16:38:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: FLUOXETINE HYDROCHLORIDE, PRODUCTSYNONYM: PROZAC - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Sep 2020 07:39:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Sep 2020 07:39:41
Data point term sent to Coder User entered 'Prozac'	System zackery harmon (b) (4)	26 Aug 2020 19:34:56 26 Aug 2020 19:34:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:34:55
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User closed query 'Per DM CLR: Indication = UNKNOWN. However, the medication was ongoing. Please review and confirm if the indication can be establish. If yes, please update eCRF as appropriate. Otherwise, provide clarification why the indication cannot be confirmed.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:55:30
User closed query 'Per CDM: As per CCG Page no: 35, 36 Please review and update the text field accordingly else clarify' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 16:55:28
Query 'Per DM CLR: Indication = UNKNOWN. However, the medication was ongoing. Please review and confirm if the indication can be establish. If yes, please update eCRF as appropriate. Otherwise, provide clarification why the indication cannot be confirmed.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 16:38:38
Query 'Per CDM: As per CCG Page no: 35, 36 Please review and update the text field accordingly else clarify' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 16:38:31
User entered 'depression' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 16:38:21
User opened query 'Per DM CLR: Indication = UNKNOWN. However, the medication was ongoing. Please review and confirm if the indication can be establish. If yes, please update eCRF as appropriate. Otherwise, provide clarification why the indication cannot be confirmed.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 10:20:24
User opened query 'Per CDM: As per CCG Page no: 35, 36 Please review and update the text field accordingly else clarify' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:35:20
User entered 'unknown'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 19:34:55

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered '40'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:34:55
	(b) (4)	

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered 'mg (mg)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:34:55
	(b) (4)	

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	26 Aug 2020 19:34:55
	(b) (4)	

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered 'once daily (QD)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:34:55
	(b) (4)	

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:41

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	26 Aug 2020 19:34:55
	(b) (4)	

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered 'Oral (ORAL)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:34:55
	(b) (4)	

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	26 Aug 2020 19:34:55
	(b) (4)	

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered 'un UNK 2018'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:34:55
	(b) (4)	

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
	(b) (4)	
User entered '0'	zackery harmon (b) (4)	26 Aug 2020 19:34:55
	(b) (4)	

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:34:55
	(b) (4)	

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	26 Aug 2020 19:34:55
	(b) (4)	

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:34:55
	(b) (4)	

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 19:34:55

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 19:34:55

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 19:34:55

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:41

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	27 Aug 2020 18:10:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:10:14
Data point term sent to Coder	System	26 Aug 2020 19:35:59
User entered 'trazadone'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 19:35:40

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:35:40
	(b) (4)	

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
	(b) (4)	
User entered 'anxiety'	zackery harmon (b) (4)	26 Aug 2020 19:35:40
	(b) (4)	

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
	(b) (4)	
User entered '10'	zackery harmon (b) (4)	26 Aug 2020 19:35:40
	(b) (4)	

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered 'mg (mg)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:35:40
	(b) (4)	

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	26 Aug 2020 19:35:40
	(b) (4)	

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered 'once daily (QD)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:35:40
	(b) (4)	

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:41

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	26 Aug 2020 19:35:40
	(b) (4)	

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered 'Oral (ORAL)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:35:40
	(b) (4)	

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	26 Aug 2020 19:35:40
	(b) (4)	

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered 'un Jun 2018'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:35:40
	(b) (4)	

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
	(b) (4)	
User entered '0'	zackery harmon (b) (4)	26 Aug 2020 19:35:40
	(b) (4)	

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:35:40
	(b) (4)	

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	26 Aug 2020 19:35:40
	(b) (4)	

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	26 Aug 2020 19:35:40
	(b) (4)	

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 19:35:40

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 19:35:40

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 19:35:40

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:41

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Feb 2021 18:26:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Feb 2021 18:26:01
Data point term sent to Coder Coding entries removed.	System Teresa Deese (b) (4)	16 Feb 2021 18:24:34 16 Feb 2021 18:23:44
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Jan 2021 15:08:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Jan 2021 15:08:06
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	19 Jan 2021 14:25:20 19 Jan 2021 14:25:04
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Nov 2020 22:00:50

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:41

Name of Medication

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. Data point term sent to Coder Coding entries removed.	Coder Import (b) (4) (b) (4) System Erica Osmundsen (b) (4) [REDACTED]	18 Nov 2020 22:00:50 18 Nov 2020 21:59:29 18 Nov 2020 21:58:32
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 06:58:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'ibuprofen'	Coder Import (b) (4) (b) (4) System (b) (4), (b) (6) [REDACTED]	17 Sep 2020 06:58:52 16 Sep 2020 16:41:33 16 Sep 2020 16:41:20

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:41:20

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered 'UPPER RESPIRATORY INFECTION' reason for change: Data Entry Error	(b) (4) Teresa Deese (b) (4)	16 Feb 2021 18:23:44
User entered 'UPPER RESPIRATORY INFECTION/HEADACHE' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Jan 2021 14:25:04
User entered 'UPPER RESPIRATORY INFECTION' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	18 Nov 2020 21:58:32
User entered 'viral infection'	(b) (4), (b) (6)	16 Sep 2020 16:41:20

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered '800'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:41:20

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:41:20

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:41:20

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:41:20

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered 'BID PRN'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:41:20

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:41:20

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:41:20

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:36:12
User closed query 'Per DM CLR: Please review the start/stop date of this medication intended for Headache as it overlaps with CM #1 IBUPROFEN (13 Aug 2020-13 Aug 2020). Please review if this is a duplicate for Headache indication. If confirmed duplicate, consider removing Headache from the Indication field. Update Con Med eCRF as appropriate. Otherwise, please clarify.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:35:31
Query 'Per DM CLR: Please review the start/stop date of this medication intended for Headache as it overlaps with CM #1 IBUPROFEN (13 Aug 2020-13 Aug 2020). Please review if this is a duplicate for Headache indication. If confirmed duplicate, consider removing Headache from the Indication field. Update Con Med eCRF as appropriate. Otherwise, please clarify.' answered with 'done' (Site from DM).	Teresa Deese (b) (4)	16 Feb 2021 18:23:54
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' answered with 'done' (Site from DM).	Teresa Deese (b) (4)	16 Feb 2021 18:23:49
User entered '09 Sep 2020' reason for change: Data Entry Error	Teresa Deese (b) (4)	16 Feb 2021 18:23:15

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review the start/stop date of this medication intended for Headache as it overlaps with CM #1 IBUPROFEN (13 Aug 2020-13 Aug 2020). Please review if this is a duplicate for Headache indication. If confirmed duplicate, consider removing Headache from the Indication field. Update Con Med eCRF as appropriate. Otherwise, please clarify.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 05:48:22
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 05:48:10
User entered '09 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Jan 2021 14:24:31
User entered '09 Sep 2020'	(b) (4), (b) (6)	16 Sep 2020 16:41:20

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:41:20

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
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) (4), (b) (6)	28 Jan 2021 15:02:37
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 'updated' (Site from DM).	zackery harmon (b) (4) (b) (4)	26 Jan 2021 17:57:41
User entered 'No (N)' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	26 Jan 2021 17:57:36
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).	(b) (4), (b) (6)	26 Jan 2021 08:55:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 16:41:20

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	(b) (4)	26 Jan 2021 17:57:36
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	26 Jan 2021 17:57:29
User entered '14 Sep 2020' reason for change: Data Entry Error	zackery harmon (b) (4)	26 Jan 2021 17:57:29
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 16:41:20

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the Indication reported is not included as one of the solicited AEs per protocol. Review and update entry as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 07:30:23
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the Indication reported is not included as one of the solicited AEs per protocol. Review and update entry as appropriate. Otherwise, clarify. ' answered with 'corrected' (Site from DM).	Erica Osmundsen (b) (4)	19 Oct 2020 19:57:38
User entered 'No (N)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	19 Oct 2020 19:57:30
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the Indication reported is not included as one of the solicited AEs per protocol. Review and update entry as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 10:50:22
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 16:41:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 16:41:25
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 16:41:25
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 16:41:20
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 16:41:20

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:14
User entered empty.	System	16 Sep 2020 16:41:20

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:14
User entered empty.	System	16 Sep 2020 16:41:20

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:14
User entered empty.	System	16 Sep 2020 16:41:20

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Nov 2020 22:00:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Nov 2020 22:00:49
Data point term sent to Coder Coding entries removed.	System Erica Osmundsen (b) (4)	18 Nov 2020 21:59:29 18 Nov 2020 21:59:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Sep 2020 16:43:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Sep 2020 16:43:38
Data point term sent to Coder User entered 'tylenol'	System (b) (4), (b) (6)	16 Sep 2020 16:42:43 16 Sep 2020 16:42:28

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:42:28

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:20
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:28:06
User entered 'UPPER RESPIRATORY INFECTION' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	18 Nov 2020 21:59:11
User entered 'viral infection'	(b) (4), (b) (6)	16 Sep 2020 16:42:28

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered '1'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:42:28

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered 'g (g)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:42:28

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:42:28

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:42:28

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered 'BID PRN'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:42:28

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:42:28

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:42:28

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered '09 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:42:28

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:42:28

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
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) (4), (b) (6)	28 Jan 2021 15:03:04
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 'updated' (Site from DM).	zackery harmon (b) (4) (b) (4)	26 Jan 2021 17:57:57
User entered 'No (N)' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	26 Jan 2021 17:57:51
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).	(b) (4), (b) (6)	26 Jan 2021 09:03:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 16:42:28

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User entered '14 Sep 2020' reason for change: Data Entry Error	(b) (4)	26 Jan 2021 17:57:51
User entered empty.	zackery harmon (b) (4)	26 Jan 2021 17:57:51
	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 16:42:28

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the Indication reported is not included as one of the solicited AEs per protocol. Review and update entry as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 08:52:24
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the Indication reported is not included as one of the solicited AEs per protocol. Review and update entry as appropriate. Otherwise, clarify. ' answered with 'corrected' (Site from DM).	Erica Osmundsen (b) (4)	19 Oct 2020 19:57:51
User entered 'No (N)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	19 Oct 2020 19:57:46
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the Indication reported is not included as one of the solicited AEs per protocol. Review and update entry as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 10:52:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 16:42:28

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:20
User entered empty.	System	16 Sep 2020 16:42:28

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:20
User entered empty.	System	16 Sep 2020 16:42:28

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:20
User entered empty.	System	16 Sep 2020 16:42:28

US3202057

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:05:41

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:28:06
	(b) (4)	
User entered 'No (N)'	zackery harmon (b) (4)	26 Aug 2020 19:33:53
	(b) (4)	