

US3202395 (Prod: WR-ClinSearch, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:41:52

All time stamps listed in this document are displayed in GMT

US3202395

Form: Participant Creation

Data signed: (b) (4) 09 Apr 2021 16:13:16

Generated On: 09 Jun 2021 15:41:52

Participant ID

US3202395

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

US3202395

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:31:31

Generated On: 09 Jun 2021 15:41:52

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 03 SEP 2020

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

Folder OID SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 02:31:31

Generated On: 09 Jun 2021 15:41:52

Date of Birth (MMM yyyy)	(b) (6) 1944
Age	76
Age Units	YEARS
Age (Derived)	76
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 02:31:31

Generated On: 09 Jun 2021 15:41:52

Date of Informed Consent (*dd MMM yyyy*) 3 SEP 2020

Month and Year of Informed Consent (derived) SEP 2020

Year of Informed Consent (derived) 2020

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

Was participant enrolled in the study? Yes
No

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

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 02:31:31

Generated On: 09 Jun 2021 15:41:52

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 02:31:31

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Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 02:31:31

Generated On: 09 Jun 2021 15:41:52

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1950
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 1950
Start Year (derived)	1950
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 02:31:31

Generated On: 09 Jun 2021 15:41:52

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2004
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 2004
Start Year (derived)	2004
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 02:31:31

Generated On: 09 Jun 2021 15:41:52

Condition	BILATERAL TUBAL LIGATION
Start date (dd MMM yyyy)	UN UNK 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1980
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	JAN 1980
Stop Year (derived)	1980

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 02:31:31

Generated On: 09 Jun 2021 15:41:52

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 1993
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1993
Start Year (derived)	1993
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Feb 2021 02:31:31

Generated On: 09 Jun 2021 15:41:52

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 13 Feb 2021 02:31:31

Generated On: 09 Jun 2021 15:41:52

Condition	LEFT BREAST BASAL CELL CANCER
Start date (dd MMM yyyy)	UN UNK 1993
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1993
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1993
Start Year (derived)	1993
Stop Month and Year (derived)	JAN 1993
Stop Year (derived)	1993

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 13 Feb 2021 02:31:31

Generated On: 09 Jun 2021 15:41:52

Condition	LUMPECTOMY LEFT BREAST
Start date (dd MMM yyyy)	UN UNK 1993
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1993
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1993
Start Year (derived)	1993
Stop Month and Year (derived)	JAN 1993
Stop Year (derived)	1993

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 13 Feb 2021 02:31:31

Generated On: 09 Jun 2021 15:41:52

Condition	LUMBAR FUSION
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2009
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JAN 2009
Stop Year (derived)	2009

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 13 Feb 2021 02:31:31

Generated On: 09 Jun 2021 15:41:52

Condition	SCIATIC NERVE PAIN
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 13 Feb 2021 02:31:31

Generated On: 09 Jun 2021 15:41:52

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 13 Feb 2021 02:31:31

Generated On: 09 Jun 2021 15:41:52

Condition	BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:31:31

Generated On: 09 Jun 2021 15:41:52

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>)	12:16 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 12:16
Height (<i>xxx.x</i>)	159.0 cm
Weight (<i>xxx.x</i>)	57.7 kg
BMI (<i>xxx.x</i>)	22.82346 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 02:31:31

Generated On: 09 Jun 2021 15:41:52

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

3 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: Screening

Form: Childbearing Potential

Data signed: (b) (4) 13 Feb 2021 02:31:31

Generated On: 09 Jun 2021 15:41:52

Date of assessment (*dd MMM yyyy*) 03 SEP 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*) UN UNK 1980

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: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 02:31:31

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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 02:31:31

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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	True
Specify	INTERACTS IN PERSON WITH 5 OR MORE PEOPLE, ATTENDED A LARGE GROUP EVENT PLANS ON GOING TO PLACES WHERE PEOPLE GATHER HUSBAND IS A PROFESSOR AT UTC

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:31:31

Generated On: 09 Jun 2021 15:41:52

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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 02:31:31

Generated On: 09 Jun 2021 15:41:52

What was the date of randomization? (dd MMM yyyy) 03 SEP 2020

What was the participant's randomization number? 189405

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

Human Immunodeficiency Virus (HIV) infection Yes No

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 02:31:31

Generated On: 09 Jun 2021 15:41:52

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 02:31:31

Generated On: 09 Jun 2021 15:41:52

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>)	03 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	12:16 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 12:16
Temperature (<i>xxx.x</i>)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	68 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3202395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:31:31

Generated On: 09 Jun 2021 15:41:52

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>)	03 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	13:57 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 13:57
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>)	64 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	85 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 02:31:31

Generated On: 09 Jun 2021 15:41:52

Was the physical examination performed?

Yes

No

Date of examination (*dd MMM yyyy*) _____

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:31:31

Generated On: 09 Jun 2021 15:41:52

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) 13:22 (24 HR)

Treatment Date and Time (derived) 3 SEP 2020 13:22

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 02:31:31

Generated On: 09 Jun 2021 15:41:52

Was the sample collected? Yes No

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

Collection time (*00:00-23:59*) 12:48 (24 HR)

Collection date and time (derived) 3 SEP 2020 12:48

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:31:31

Generated On: 09 Jun 2021 15:41:52

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	12:24	3 SEP 2020 12:24
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:31:31

Generated On: 09 Jun 2021 15:41:52

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

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 13:57
PC Open Date & Time 03 SEP 2020 13:42
PC Close Date & Time 03 SEP 2020 16:12

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

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 98.6 °F

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

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

PC Time Stamp 03 SEP 2020 21:23
PC Open Date & Time 03 SEP 2020 17:07
PC Close Date & Time 04 SEP 2020 11:59

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:52

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	98.2 °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	04 SEP 2020 20:41
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:52

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	97.3 °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	05 SEP 2020 21:46
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:52

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	98.2 °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 21:46
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:52

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 20:13
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:52

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	97.6 °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 21:26
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:52

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 <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 SEP 2020 21:14
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

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 13:58

PC Open Date & Time

03 SEP 2020 13:42

PC Close Date & Time

03 SEP 2020 16:12

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

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 21:24

PC Open Date & Time

03 SEP 2020 17:07

PC Close Date & Time

04 SEP 2020 11:59

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:52

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 20:41

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:52

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	05 SEP 2020 21:46
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:52

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 21:46

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:52

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 20:13
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:52

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 21:26
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:52

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

09 SEP 2020 21:14

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

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

No

Yes

PC Time stamp	03 SEP 2020 13:58
PC Open Date & Time	03 SEP 2020 13:42
PC Close Date & Time	03 SEP 2020 16:12

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

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

No

Yes

PC Time stamp	03 SEP 2020 21:25
PC Open Date & Time	03 SEP 2020 17:07
PC Close Date & Time	04 SEP 2020 11:59

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:52

	Yes <input type="checkbox"/>
PC Time stamp	04 SEP 2020 20:42
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:52

	Yes <input type="checkbox"/>
PC Time stamp	05 SEP 2020 21:46
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:52

	Yes <input type="checkbox"/>
PC Time stamp	06 SEP 2020 21:46
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:52

	Yes <input type="checkbox"/>
PC Time stamp	07 SEP 2020 20:13
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:52

	Yes <input type="checkbox"/>
PC Time stamp	08 SEP 2020 21:26
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:52

	Yes <input type="checkbox"/>
PC Time stamp	09 SEP 2020 21:15
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3202395

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:31:31

Generated On: 09 Jun 2021 15:41:52

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 10 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3202395

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:31:31

Generated On: 09 Jun 2021 15:41:52

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3202395

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:31:31

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:31:31

Generated On: 09 Jun 2021 15:41:52

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3202395

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:31:31

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:31:31

Generated On: 09 Jun 2021 15:41:52

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3202395

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:31:31

Generated On: 09 Jun 2021 15:41:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 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	VISIT2

US3202395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:31:42

Generated On: 09 Jun 2021 15:41:52

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 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	11:03 (24 HR)
Vital Signs Date and Time (derived)	07 OCT 2020 11:03
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>)	66 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3202395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:31:42

Generated On: 09 Jun 2021 15:41:52

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 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	12:17 (24 HR)
Vital Signs Date and Time (derived)	07 OCT 2020 12:17
Temperature (<i>xxx.x</i>)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	57 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3202395

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:31:31

Generated On: 09 Jun 2021 15:41:52

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.

US3202395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:31:31

Generated On: 09 Jun 2021 15:41:52

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 OCT 2020

What was the treatment time? (00:00-23:59) 11:42 (24 HR)

Treatment Date and Time (derived) 7 OCT 2020 11:42

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

US3202395

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:31:31

Generated On: 09 Jun 2021 15:41:52

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	7 OCT 2020
Collection time (<i>00:00-23:59</i>)	11:25 (24 HR)
Collection date and time (derived)	7 OCT 2020 11:25

US3202395

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:31:31

Generated On: 09 Jun 2021 15:41:52

Collection date (<i>dd MMM yyyy</i>)			7 OCT 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:11	7 OCT 2020 11:11
Nasopharyngeal Swab 2	No		

US3202395

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:31:31

Generated On: 09 Jun 2021 15:41:52

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

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 98.6 °F

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

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

PC Time Stamp 07 OCT 2020 12:25

PC Open Date & Time 07 OCT 2020 12:02

PC Close Date & Time 07 OCT 2020 14:32

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

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 98.8 °F

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

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

PC Time Stamp 07 OCT 2020 20:53
PC Open Date & Time 07 OCT 2020 15:27
PC Close Date & Time 08 OCT 2020 11:59

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:52

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	98.4 °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	08 OCT 2020 20:09
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:52

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	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 OCT 2020 21:42
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:52

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	98.0 °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	10 OCT 2020 21:16
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:52

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	98.6 °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	11 OCT 2020 22:18
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:52

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	98.5 °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	12 OCT 2020 22:04
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:52

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 96.3 °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):

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

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

PC Time Stamp 13 OCT 2020 20:58

PC Open Date & Time 13 OCT 2020 12:00

PC Close Date & Time 14 OCT 2020 11:59

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:41:52

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 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 14 OCT 2020 19:24

PC Open Date & Time 14 OCT 2020 12:00

PC Close Date & Time 15 OCT 2020 11:59

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:41:52

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	97.6 °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	15 OCT 2020 22:24
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

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 OCT 2020 12:25

PC Open Date & Time

07 OCT 2020 12:02

PC Close Date & Time

07 OCT 2020 14:32

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

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 OCT 2020 20:55

PC Open Date & Time

07 OCT 2020 15:27

PC Close Date & Time

08 OCT 2020 11:59

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:52

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	08 OCT 2020 20:10
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:52

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 OCT 2020 21:42
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:52

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 OCT 2020 21:16

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:52

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 OCT 2020 22:18
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:52

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 OCT 2020 22:04

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:52

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 OCT 2020 20:59
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

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

No

Yes

PC Time stamp	07 OCT 2020 12:26
PC Open Date & Time	07 OCT 2020 12:02
PC Close Date & Time	07 OCT 2020 14:32

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

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

No

Yes

PC Time stamp	07 OCT 2020 20:56
PC Open Date & Time	07 OCT 2020 15:27
PC Close Date & Time	08 OCT 2020 11:59

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:52

	Yes <input type="checkbox"/>
PC Time stamp	08 OCT 2020 20:10
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:52

	Yes <input type="checkbox"/>
PC Time stamp	09 OCT 2020 21:43
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:52

	Yes <input type="checkbox"/>
PC Time stamp	10 OCT 2020 21:16
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:52

	Yes <input type="checkbox"/>
PC Time stamp	11 OCT 2020 22:18
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:52

	Yes <input type="checkbox"/>
PC Time stamp	12 OCT 2020 22:05
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:52

	Yes <input type="checkbox"/>
PC Time stamp	13 OCT 2020 21:00
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3202395

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:41:52

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 OCT 2020 19:25

PC Open Date & Time 14 OCT 2020 12:00

PC Close Date & Time 15 OCT 2020 11:59

US3202395

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:41:52

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 OCT 2020 22:23

PC Open Date & Time 15 OCT 2020 12:00

PC Close Date & Time 16 OCT 2020 11:59

US3202395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:41:52

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 OCT 2020 19:25

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3202395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:41:52

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 OCT 2020 22:23

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3202395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:41:52

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

16 OCT 2020 21:39

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3202395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 15:41:52

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

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3202395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

DAY 12

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

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3202395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:41:52

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 OCT 2020 19:26
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3202395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:41:52

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 OCT 2020 22:24
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3202395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:41:52

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	16 OCT 2020 21:39
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3202395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/> Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3202395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/> Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3202395

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:31:31

Generated On: 09 Jun 2021 15:41:52

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 14 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3202395

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:31:31

Generated On: 09 Jun 2021 15:41:52

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3202395

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:31:31

Generated On: 09 Jun 2021 15:41:52

Was Contact Attempted? Yes
No

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

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

Comments LVM ATTEMPTS X3

If Contact Not Made, please provide Comments

US3202395

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:31:31

Generated On: 09 Jun 2021 15:41:52

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3202395

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:31:31

Generated On: 09 Jun 2021 15:41:52

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 28 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3202395

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:31:31

Generated On: 09 Jun 2021 15:41:52

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3202395

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:31:43

Generated On: 09 Jun 2021 15:41:52

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 04 NOV 2020

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

Folder OID VISIT3

US3202395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:31:43

Generated On: 09 Jun 2021 15:41:52

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	04 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	10:44 (24 HR)
Vital Signs Date and Time (derived)	04 NOV 2020 10:44
Temperature (<i>xxx.x</i>)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	84 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3202395

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:31:42

Generated On: 09 Jun 2021 15:41:52

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.

US3202395

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:31:42

Generated On: 09 Jun 2021 15:41:52

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 04 NOV 2020

Collection time (*00:00-23:59*) 10:53 (24 HR)

Collection date and time (derived) 04 NOV 2020 10:53

US3202395

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:31:42

Generated On: 09 Jun 2021 15:41:52

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3202395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

DAY 64

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

No

Yes

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

No

Yes

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

Date and time of submission 04 NOV 2020 21:40:00

Patient Cloud Open Date & Time 03 NOV 2020 00:01

Patient Cloud Close Date & Time 07 NOV 2020 23:59

US3202395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

DAY 71

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

No

Yes

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

No

Yes

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

Date and time of submission 10 NOV 2020 17:54:50

Patient Cloud Open Date & Time 10 NOV 2020 00:01

Patient Cloud Close Date & Time 14 NOV 2020 23:59

US3202395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

DAY 78

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

No

Yes

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

No

Yes

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

Date and time of submission	17 NOV 2020 09:16:55
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

DAY 82

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

No

Yes

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

No

Yes

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

Date and time of submission 24 NOV 2020 08:44:16

Patient Cloud Open Date & Time 21 NOV 2020 00:01

Patient Cloud Close Date & Time 25 NOV 2020 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

DAY 89

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2020 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

DAY 96

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

DAY 103

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

No

Yes

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

No

Yes

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

Date and time of submission 14 DEC 2020 09:00:57

Patient Cloud Open Date & Time 12 DEC 2020 00:01

Patient Cloud Close Date & Time 16 DEC 2020 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	22 DEC 2020 19:17:51
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

DAY 117

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission	
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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	02 JAN 2021 16:34:15
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

DAY 131

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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 JAN 2021 13:44:37
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

DAY 145

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

DAY 152

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

No

Yes

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

No

Yes

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

Date and time of submission 01 FEB 2021 20:24:38

Patient Cloud Open Date & Time 30 JAN 2021 00:01

Patient Cloud Close Date & Time 03 FEB 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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	06 FEB 2021 22:30:15
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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 <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	13 FEB 2021 22:41:07
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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 20 FEB 2021 08:54:52

Patient Cloud Open Date & Time 20 FEB 2021 00:01

Patient Cloud Close Date & Time 24 FEB 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

DAY 180

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

No

Yes

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

No

Yes

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

Date and time of submission

01 MAR 2021 07:45:58

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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	06 MAR 2021 08:08:58
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 MAR 2021 07:39:22
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 MAR 2021 15:31:40
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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	28 MAR 2021 10:50:52
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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	03 APR 2021 08:41:12
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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 <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	11 APR 2021 08:52:05
Patient Cloud Open Date & Time	10 APR 2021 00:01
Patient Cloud Close Date & Time	14 APR 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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	17 APR 2021 18:55:43
Patient Cloud Open Date & Time	17 APR 2021 00:01
Patient Cloud Close Date & Time	21 APR 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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	25 APR 2021 10:24:00
Patient Cloud Open Date & Time	24 APR 2021 00:01
Patient Cloud Close Date & Time	28 APR 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

DAY 243

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

DAY 250

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

DAY 257

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

Patient Cloud Open Date & Time	15 MAY 2021 00:01
Patient Cloud Close Date & Time	19 MAY 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

DAY 264

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission	
Patient Cloud Open Date & Time	17 JUL 2021 00:01
Patient Cloud Close Date & Time	21 JUL 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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°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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

Patient Cloud Open Date & Time	14 AUG 2021 00:01
Patient Cloud Close Date & Time	18 AUG 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#) 29 SEP 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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°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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

DAY 404

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#) 13 OCT 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission	
Patient Cloud Open Date & Time	13 NOV 2021 00:01
Patient Cloud Close Date & Time	17 NOV 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

DAY 446

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission	
Patient Cloud Open Date & Time	27 NOV 2021 00:01
Patient Cloud Close Date & Time	01 DEC 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

Patient Cloud Open Date & Time	11 DEC 2021 00:01
Patient Cloud Close Date & Time	15 DEC 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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°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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#) 02 FEB 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

Patient Cloud Open Date & Time	05 FEB 2022 00:01
Patient Cloud Close Date & Time	09 FEB 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

Patient Cloud Open Date & Time	12 FEB 2022 00:01
Patient Cloud Close Date & Time	16 FEB 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 02 APR 2022 00:01

[Patient Cloud Close Date & Time](#) 06 APR 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission	
Patient Cloud Open Date & Time	23 APR 2022 00:01
Patient Cloud Close Date & Time	27 APR 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

DAY 607

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

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

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

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

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

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

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

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

Patient Cloud Open Date & Time	02 JUL 2022 00:01
Patient Cloud Close Date & Time	06 JUL 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission	
Patient Cloud Open Date & Time	09 JUL 2022 00:01
Patient Cloud Close Date & Time	13 JUL 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

DAY 691

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

DAY 698

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

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

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

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

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

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

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

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

DAY 740

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

Patient Cloud Open Date & Time	01 OCT 2022 00:01
Patient Cloud Close Date & Time	05 OCT 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

Patient Cloud Open Date & Time	08 OCT 2022 00:01
Patient Cloud Close Date & Time	12 OCT 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3202395

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:41:52

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		01 MAR 2021 07:46:18

US3202395

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 12:55:20

Generated On: 09 Jun 2021 15:41:52

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 3 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3202395

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 12:55:20

Generated On: 09 Jun 2021 15:41:52

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3202395

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 16:13:17

Generated On: 09 Jun 2021 15:41:52

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 5 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3202395

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 16:13:17

Generated On: 09 Jun 2021 15:41:52

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3202395

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 16:13:48

Generated On: 09 Jun 2021 15:41:52

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 9 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3202395

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 16:13:17

Generated On: 09 Jun 2021 15:41:52

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3202395

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 16:13:48

Generated On: 09 Jun 2021 15:41:52

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (dd MMM yyyy) 1 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3202395

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 16:13:48

Generated On: 09 Jun 2021 15:41:52

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3202395

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 16:13:49

Generated On: 09 Jun 2021 15:41:52

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 5 APR 2021

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

Folder OID VISIT4

US3202395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 16:13:49

Generated On: 09 Jun 2021 15:41:52

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) _____

US3202395

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 16:13:49

Generated On: 09 Jun 2021 15:41:52

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.

US3202395

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 16:13:49

Generated On: 09 Jun 2021 15:41:52

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 5 APR 2021

Collection time (*00:00-23:59*) 10:46 (24 HR)

Collection date and time (derived) 5 APR 2021 10:46

US3202395

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 16:13:49

Generated On: 09 Jun 2021 15:41:52

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3202395

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

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 _____

US3202395

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:52

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3202395

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 09 Apr 2021 16:13:17

Generated On: 09 Jun 2021 15:41:52

Date of Contact	29 SEP 2020
Time of Contact	09:30
Date and Time of Contact (derived)	29 SEP 2020 09:30
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/> Clinical Visit - Unscheduled <input checked="" type="checkbox"/> Safety Call <input 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"/>

US3202395

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 09 Apr 2021 16:13:17

Generated On: 09 Jun 2021 15:41:52

Date of Visit 29 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 29 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

US3202395

Folder: Covid-19 Assessment 29 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 09 Apr 2021 16:13:17

Generated On: 09 Jun 2021 15:41:52

[Generate Next COVID-19 Assessment](#)

Yes

No

US3202395

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 09 Apr 2021 16:13:17

Generated On: 09 Jun 2021 15:41:52

Visit	Was Saliva Collected?	Date of Collection
Day 3	No	
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)	

US3202395

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 16:13:17

Generated On: 09 Jun 2021 15:41:52

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 29 SEP 2020

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

Folder OID SICKD1

US3202395

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 16:13:17

Generated On: 09 Jun 2021 15:41:52

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	29 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	09:40 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 09:40
Height (<i>xxx.x</i>)	159 cm
Weight (<i>xxx.x</i>)	56.6 kg
Temperature (<i>xxx.x</i>)	37.0 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>)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3202395

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 16:13:17

Generated On: 09 Jun 2021 15:41:52

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

29 SEP 2020

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

US3202395

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 16:13:17

Generated On: 09 Jun 2021 15:41:52

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

Yes

No

NA (COVID-19 Negative)

Date of Collection

29 SEP 2020

US3202395

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 16:13:17

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 16:13:17

Generated On: 09 Jun 2021 15:41:52

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) _____

US3202395

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 16:13:17

Generated On: 09 Jun 2021 15:41:52

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.

US3202395

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 16:13:17

Generated On: 09 Jun 2021 15:41:52

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

Yes

No

NA (COVID-19 Negative)

Date of Collection _____

US3202395

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

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 16:13:17

Generated On: 09 Jun 2021 15:41:52

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 1 FEB 2021

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

Folder OID UNBLND_DECIDE

US3202395

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

Form: Unblinding

Data signed: (b) (4) 09 Apr 2021 16:13:17

Generated On: 09 Jun 2021 15:41:52

Date of updated informed consent (<i>dd MMM yyyy</i>)	1 FEB 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>)	1 FEB 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

US3202395

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 09 Apr 2021 16:13:17

Generated On: 09 Jun 2021 15:41:52

Height	_____
Weight	_____
BMI (xxx.x)	_____

US3202395

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Apr 2021 16:13:17

Generated On: 09 Jun 2021 15:41:52

Height	_____
Weight	_____
BMI (xxx.x)	_____
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)	1 FEB 2021
Time of assessment (00:00-23:59)	12:25 (24 HR)
Vital Signs Date and Time (derived)	1 FEB 2021 12:25
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3202395

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Apr 2021 16:13:17

Generated On: 09 Jun 2021 15:41:52

Height	_____
Weight	_____
BMI (xxx.x)	_____
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)	1 FEB 2021
Time of assessment (00:00-23:59)	13:20 (24 HR)
Vital Signs Date and Time (derived)	1 FEB 2021 13:20
Temperature (xxx.x)	35.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3202395

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

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 16:13:17

Generated On: 09 Jun 2021 15:41:52

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.

US3202395

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

Form: Exposure

Data signed: (b) (4) 09 Apr 2021 16:13:17

Generated On: 09 Jun 2021 15:41:52

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) 1 FEB 2021

What was the treatment time? (00:00-23:59) 12:34 (24 HR)

Treatment Date and Time (derived) 1 FEB 2021 12:34

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

US3202395

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 16:13:17

Generated On: 09 Jun 2021 15:41:52

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 1 FEB 2021

Collection time (*00:00-23:59*) 12:29 (24 HR)

Collection date and time (derived) 1 FEB 2021 12:29

US3202395

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 09 Apr 2021 16:13:17

Generated On: 09 Jun 2021 15:41:52

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 1 FEB 2021

Collection time (*00:00 - 23:59*) 12:24

Collection Date and Time (derived) 1 FEB 2021 12:24

US3202395

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

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 16:13:17

Generated On: 09 Jun 2021 15:41:52

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3202395

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 16:13:49

Generated On: 09 Jun 2021 15:41:52

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 9 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3202395

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 16:13:49

Generated On: 09 Jun 2021 15:41:52

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3202395

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 16:13:17

Generated On: 09 Jun 2021 15:41:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 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	OLD29

US3202395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Apr 2021 16:13:17

Generated On: 09 Jun 2021 15:41:52

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>)	1 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	13:17 (24 HR)
Vital Signs Date and Time (derived)	1 MAR 2021 13:17
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>)	65 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	63 mmHg
Diastolic Blood Pressure units	MMHG

US3202395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Apr 2021 16:13:17

Generated On: 09 Jun 2021 15:41:52

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>)	1 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	13:57 (24 HR)
Vital Signs Date and Time (derived)	1 MAR 2021 13:57
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>)	76 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 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>)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3202395

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 16:13:17

Generated On: 09 Jun 2021 15:41:52

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.

US3202395

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 09 Apr 2021 16:13:17

Generated On: 09 Jun 2021 15:41:52

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) 1 MAR 2021

What was the treatment time? (00:00-23:59) 13:27 (24 HR)

Treatment Date and Time (derived) 1 MAR 2021 13:27

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

US3202395

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 16:13:17

Generated On: 09 Jun 2021 15:41:52

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3202395

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 16:13:49

Generated On: 09 Jun 2021 15:41:52

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 9 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3202395

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 16:13:49

Generated On: 09 Jun 2021 15:41:52

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

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Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 16:13:17

Generated On: 09 Jun 2021 15:41:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 APR 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

US3202395

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 16:13:17

Generated On: 09 Jun 2021 15:41:52

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) _____

US3202395

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 16:13:17

Generated On: 09 Jun 2021 15:41:52

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.

US3202395

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 16:13:17

Generated On: 09 Jun 2021 15:41:52

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 5 APR 2021

Collection time (*00:00-23:59*) 10:46 (24 HR)

Collection date and time (derived) 5 APR 2021 10:46

US3202395

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Apr 2021 17:20:24

Generated On: 09 Jun 2021 15:41:52

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3202395

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

AEID USA-US128-2021-MRNA-1273-P30
1000018

Adverse event DYSPNEA ON EXERTION

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) 06 APR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

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

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 8 APR 2021

Hospital Discharge Date (dd MMM yyyy) 9 APR 2021

Admitted to ICU? Yes
No
Unknown

US3202395

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

Number of Days in ICU _____

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

Action taken with investigational product None
Dose Delayed
Investigational Product
Withdrawn
Not Applicable

Other action taken (check all that apply)

None True

Concomitant Medication False

Concomitant Procedure False

Outcome Fatal
Not Recovered/Not Resolved
Recovered/Resolved
Recovered/Resolved with
Sequelae
Recovering/Resolving
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative _____

US3202395

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

SUBJECT PRESENTED AT THE ER ON 08APR2021 REPORTING 2 DAYS OF DYSPNEA ON EXERTION AND HAD JUST HAD AN EPISODE OF WEAKNESS AND HEAVINESS IN CHEST WITH DYSPNEA ON 08APR21, WHICH PROMPTED THE ER VISIT. SHE WAS KEPT OVERNIGHT FOR EVALUATION PER CARDIAC PROTOCOL BUT NO CARDIAC FINDINGS--CATHETERIZATION NEGATIVE FOR BLOCKAGE, BIOMARKER LABS NORMAL, EKG NORMAL. SHE DID HAVE LOW POTASSIUM AND MAGNESIUM NOTED IN CHART, DISCHARGED WITH NON-CARDIAC CHEST PAIN AND WILL F/UP WITH PCP AND CARDIOLOGY

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

US3202395

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

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)	13 OCT 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)	15 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
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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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

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 type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	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)	_____

US3202395

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

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)	12 OCT 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)	16 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
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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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

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 type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	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)	_____

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

AEID

Adverse event

ELECTROLYTE
ABNORMALITIES

Was this a medically-attended AE?

Yes

No

Was this a Solicited Adverse Reaction?

Yes

No

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

Yes

No

Start date (dd MMM yyyy)

08 APR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

09 APR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild

Grade 2/Moderate

Grade 3/Severe

Grade 4

Is the adverse event serious?

Yes

No

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes

No

Unknown

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

Number of Days in ICU _____

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

Action taken with investigational product None
Dose Delayed
Investigational Product
Withdrawn
Not Applicable

Other action taken (check all that apply)

None False

Concomitant Medication True

Concomitant Procedure False

Outcome Fatal
Not Recovered/Not Resolved
Recovered/Resolved
Recovered/Resolved with
Sequelae
Recovering/Resolving
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative

US3202395

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

SUBJECT PRESENTED AT ER
FOR DYSPNEA ON EXERTION
AND WAS FOUND TO HAVE
LOW POTASSIUM AND
MAGNESIUM ON ADMISSION
LABS--PLACED ON
ELECTROLYTE REPLACEMENT
PROTOCOL AND LEVELS WERE
NO LONGER LOW UPON
REPEAT LABS PRIOR TO
DISCHARGE THE FOLLOWING
DAY. THESE WERE NOT THE
REASON FOR
HOSPITALIZATION NOR WERE
THEY SEVERELY DEFICIENT.

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

US3202395

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

AEID

Adverse event

NON-CARDIAC CHEST PAIN OF
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)

08 APR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

08 APR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild

Grade 2/Moderate

Grade 3/Severe

Grade 4

Is the adverse event serious?

Yes

No

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes

No

Unknown

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

Number of Days in ICU _____

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

Action taken with investigational product None
Dose Delayed
Investigational Product
Withdrawn
Not Applicable

Other action taken (check all that apply)

None True

Concomitant Medication False

Concomitant Procedure False

Outcome Fatal
Not Recovered/Not Resolved
Recovered/Resolved
Recovered/Resolved with
Sequelae
Recovering/Resolving
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative _____

US3202395

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

SUBJECT PRESENTED AT ER FOR PERSISTENT DYSPNEA UPON EXERTION AND ONE EPISODE OF CHEST PAIN. SHE WAS ADMITTED OVERNIGHT FOR EVALUATION AND CARDIAC WORKUP BUT ALL CARDIAC TESTS WERE NEGATIVE (NORMAL ECG, NO STENOSIS FOUND ON CATHETERIZATION, CARDIAC BIOMARKER LABS ALL NORMAL). NITROGLYCERIN WAS ORDERED AS PRN, BUT WAS NOT USED SO NO TREATMENT NOTED FOR THIS AE AS OF THIS TIME.

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

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Apr 2021 16:13:17

Generated On: 09 Jun 2021 15:41:52

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

Yes

No

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

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

Name of Medication SIMVASTATIN

Prophylaxis Yes
No

Indication HYPERCHOLESTEROLEMIA

Dose per administration 10

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

	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 2004

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

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

Name of Medication TRAMADOL

Prophylaxis Yes
No

Indication SCIATIC NERVE PAIN

Dose per administration 50

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

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 2008

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) 3

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

Name of Medication TRIAMTERENE HCTZ

Prophylaxis Yes
No

Indication HYPERTENSION

Dose per administration 37.5/25

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

	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 2008

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

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

Name of Medication LEVOTHYROXINE

Prophylaxis Yes
No

Indication HYPOTHYROIDISM

Dose per administration 88

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

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

	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 1993

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

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

Name of Medication GABAPENTIN

Prophylaxis Yes
No

Indication SCIATIC NERVE PAIN

Dose per administration 100

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

	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 MAR 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

Name of Medication FISH OIL

Prophylaxis Yes
No

Indication SUPPLEMENT

Dose per administration 4

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2010

Start date completely unknown False

Ongoing? Yes
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

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

Name of Medication VITAMIN B12

Prophylaxis Yes
No

Indication SUPPLEMENT

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2010

Start date completely unknown False

Ongoing? Yes
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

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

Name of Medication CITRUS BIOFLAVONOIDS

Prophylaxis Yes
No

Indication SUPPLEMENT

Dose per administration 250

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

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2010

Start date completely unknown False

Ongoing? Yes
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

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

Name of Medication NIACINAMIDE

Prophylaxis Yes
No

Indication SUPPLEMENT

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2010

Start date completely unknown False

Ongoing? Yes
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

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

Name of Medication COQ10

Prophylaxis Yes
No

Indication SUPPLEMENT

Dose per administration 100

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2010

Start date completely unknown False

Ongoing? Yes
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

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

Name of Medication MILK THISTLE

Prophylaxis Yes
No

Indication SUPPLEMENT

Dose per administration 175

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

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 MAR 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

Name of Medication TUMERIC

Prophylaxis Yes
No

Indication SUPPLEMENT

Dose per administration 700

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 (12)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2010

Start date completely unknown False

Ongoing? Yes
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

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

Name of Medication GINKO BILOBA

Prophylaxis Yes
No

Indication SUPPLEMENT

Dose per administration 80

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2010

Start date completely unknown False

Ongoing? Yes
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

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

Name of Medication MAGNESIUM CITRATE

Prophylaxis Yes
No

Indication SUPPLEMENT

Dose per administration 420

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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US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2010

Start date completely unknown False

Ongoing? Yes
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

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

Name of Medication VITAMIN D3 & K2

Prophylaxis Yes
No

Indication SUPPLEMENT

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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US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2010

Start date completely unknown False

Ongoing? Yes
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

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

Name of Medication BIOTEN PLUS LUTEIN

Prophylaxis Yes
No

Indication SUPPLEMENT

Dose per administration 5

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2010

Start date completely unknown False

Ongoing? Yes
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

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

Name of Medication GLUCOSAMINE SULFATE

Prophylaxis Yes
No

Indication SUPPLEMENT

Dose per administration 750

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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US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2010

Start date completely unknown False

Ongoing? Yes
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

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

Name of Medication CHOLINE BITARTRATE

Prophylaxis Yes
No

Indication SUPPLEMENT

Dose per administration 250

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 (18)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2010

Start date completely unknown False

Ongoing? Yes
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

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

Name of Medication TYLENOL

Prophylaxis Yes
No

Indication BACK PAIN
DIARY ENTRY HEADACHE CON
MED

Dose per administration 500

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 13 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

Name of Medication IBUPROFEN

Prophylaxis Yes
No

Indication CHRONIC BACK PAIN

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

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

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*) 15 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

Name of Medication ASPIRIN

Prophylaxis Yes
No

Indication CARDIOVASCULAR
PROPHYLAXIS

Dose per administration 81

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

	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 APR 2021

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

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

Name of Medication POTASSIUM SUPPLEMENT

Prophylaxis Yes
No

Indication ELECTROLYTE
ABNORMALITIES

Dose per administration 20

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify MEQ/HOUR

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

	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 checked="" 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) 08 APR 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 09 APR 2021

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

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

Name of Medication MAGNESIUM REPLACEMENT

Prophylaxis Yes
No

Indication ELECTROLYTE
ABNORMALITIES

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify G/HR

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 22 Apr 2021 18:04:05

Generated On: 09 Jun 2021 15:41:52

	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 checked="" 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) 08 APR 2021

Start date completely unknown False

Ongoing? Yes

No

If not Ongoing, End date (dd MMM yyyy) 09 APR 2021

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

US3202395

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 16:13:17

Generated On: 09 Jun 2021 15:41:52

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3202395

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:41:52

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

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Data signed: (b) (4) 22 Apr 2021 18:04:06

Generated On: 09 Jun 2021 15:41:52

SAEID	USA-US128-2021-MRNA-1273-P30 1000018
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	_____
Site Address: City	_____
Site Address: State	_____
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form (1)

Data signed: (b) (4) 22 Apr 2021 18:04:06

Generated On: 09 Jun 2021 15:41:52

SAEID	USA-US128-2021-MRNA-1273-P301000018
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	13/APR/2021 06:18
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	<input checked="" type="checkbox"/> True

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form (2)

Data signed: (b) (4) 22 Apr 2021 18:04:06

Generated On: 09 Jun 2021 15:41:52

SAEID	USA-US128-2021-MRNA-1273-P30 1000018
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	_____
Site Address: City	_____
Site Address: State	_____
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	20/APR/2021 12:08
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form (3)

Data signed: (b) (4) 22 Apr 2021 18:04:06

Generated On: 09 Jun 2021 15:41:52

SAEID	USA-US128-2021-MRNA-1273-P301000018
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	_____
Site Address: City	_____
Site Address: State	_____
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	21/APR/2021 09:35
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	<input checked="" type="checkbox"/> True

Audit

US3202395 (Prod: WR-ClinSearch, LLC)

US3202395

Form: Participant Creation

Generated On: 09 Jun 2021 15:41:52

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 21:53:45
User entered 'US3202395'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 15:54:52

US3202395

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:41:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 17:45:58

US3202395

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '03 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 15:54:53

US3202395

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:41:52

[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 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Clinic (Clinic)'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 17:45:58

US3202395

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:41:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered 'SCRN'	System	03 Sep 2020 17:45:58

US3202395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:52

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered (b) (6) 1944'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 15:54:54

US3202395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:52

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '76'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 22:20:43

US3202395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:52

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered 'YEARS'	System	03 Sep 2020 22:20:43

US3202395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:52

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered '76'	System	03 Sep 2020 17:46:11

US3202395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:52

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User closed query 'Per CDM: Sex is recoded as 'Female'. however childbearing potential should be Indicated as 'Yes or No'. Please review and update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:53:08
Query 'Per CDM: Sex is recoded as 'Female'. however childbearing potential should be Indicated as 'Yes or No'. Please review and update accordingly. ' answered with 'fixed' (Site from DM).	zackery harmon (b) (4) (b) (4)	15 Sep 2020 14:37:58
User opened query 'Per CDM: Sex is recoded as 'Female'. however childbearing potential should be Indicated as 'Yes or No'. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:38:37
User entered 'Female (F)'	Tiffany Jewell (b) (4) (b) (4)	03 Sep 2020 22:20:43

US3202395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:52

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 22:20:43

US3202395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:52

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '1'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 22:20:43

US3202395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:52

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '0'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 22:20:43

US3202395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:52

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '0'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 22:20:43

US3202395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:52

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '0'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 22:20:43

US3202395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:52

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '0'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 22:20:43

US3202395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:52

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '0'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 22:20:43

US3202395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:52

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 22:20:43

US3202395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:52

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '0'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 22:20:43

US3202395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:52

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '0'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 22:20:43

US3202395

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:41:52

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:33:35
User entered '3 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	03 Sep 2020 17:46:11

US3202395

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered 'Sep 2020'	System	03 Sep 2020 17:46:11

US3202395

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered '2020'	System	03 Sep 2020 17:46:11

US3202395

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:41:52

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:33:35
User entered 'Amendment 3 (3)'	Tiffany Jewell (b) (4) (b) (4)	03 Sep 2020 17:46:11

US3202395

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:33:35
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	03 Sep 2020 17:46:11

US3202395

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:41:52

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:33:35
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	03 Sep 2020 17:46:11

US3202395

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:41:52

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:33:35
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	03 Sep 2020 17:46:11

US3202395

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:41:52

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:33:35
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	03 Sep 2020 17:46:11

US3202395

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:41:52

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:33:35
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 15:54:53

US3202395

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:41:52

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered '1'	System	03 Sep 2020 17:46:15

US3202395

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 17:46:15

US3202395

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:41:52

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:05:15
	(b) (4)	

US3202395

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:41:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
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)	02 Oct 2020 17:51:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 17:51:52
Data point term sent to Coder	System	02 Oct 2020 17:51:04
User entered 'SEASONAL ALLERGIES'	(b) (4), (b) (6)	02 Oct 2020 17:50:38

US3202395

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'UN UNK 1950'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:50:38

US3202395

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:41:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:50:38

US3202395

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:41:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:50:38

US3202395

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:50:38

US3202395

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:41:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:50:38

US3202395

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:41:52

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered 'Jan 1950'	System	02 Oct 2020 17:50:38

US3202395

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:41:52

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered '1950'	System	02 Oct 2020 17:50:38

US3202395

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered empty.	System	02 Oct 2020 17:50:38

US3202395

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered empty.	System	02 Oct 2020 17:50:38

US3202395

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:41:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\23.0.	Coder Import (b) (4)	02 Oct 2020 17:52:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Oct 2020 17:52:57
Data point term sent to Coder	System	02 Oct 2020 17:52:05
User entered 'HYPERCHOLESTEROLEMIA'	(b) (4), (b) (6)	02 Oct 2020 17:51:20

US3202395

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'UN UNK 2004'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:51:20

US3202395

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:41:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:51:20

US3202395

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:41:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:51:20

US3202395

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:51:20

US3202395

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:41:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:51:20

US3202395

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:41:52

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered 'Jan 2004'	System	02 Oct 2020 17:51:20

US3202395

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:41:52

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered '2004'	System	02 Oct 2020 17:51:20

US3202395

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered empty.	System	02 Oct 2020 17:51:20

US3202395

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered empty.	System	02 Oct 2020 17:51:20

US3202395

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:41:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\23.0.	Coder Import (b) (4)	10 Oct 2020 19:59:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Oct 2020 19:59:25
Data point term sent to Coder	System	10 Oct 2020 19:58:02
Coding entries removed.	Tiffany Jewell (b) (4)	10 Oct 2020 19:57:37
User entered 'Bilateral TUBAL LIGATION' reason for change: Data Entry Error	Tiffany Jewell (b) (4)	10 Oct 2020 19:57:37
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\23.0.	Coder Import (b) (4)	02 Oct 2020 17:52:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Oct 2020 17:52:56
Data point term sent to Coder	System	02 Oct 2020 17:52:05
User entered 'TUBAL LIGATION'	(b) (4), (b) (6)	02 Oct 2020 17:52:04

US3202395

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'UN UNK 1980'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:52:04

US3202395

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:41:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:52:04

US3202395

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:41:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:35:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 17:52:04

US3202395

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User closed query 'Per CDM: Surgical/medical procedure TUBAL LIGATION (start UN UNK 1980) condition ongoing at study entry recorded as "YES"? Please review and provide an 'actual stop date' for when this medical procedure was completed., else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:36:49
Query 'Per CDM: Surgical/medical procedure TUBAL LIGATION (start UN UNK 1980) condition ongoing at study entry recorded as "YES"? Please review and provide an 'actual stop date' for when this medical procedure was completed., else clarify.' answered with 'QUERY CORRECTED' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 14:36:11
User entered 'UN UNK 1980' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 14:35:45
User opened query 'Per CDM: Surgical/medical procedure TUBAL LIGATION (start UN UNK 1980) condition ongoing at study entry recorded as "YES"? Please review and provide an 'actual stop date' for when this medical procedure was completed., else clarify.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 09:42:37
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 17:52:04

US3202395

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:41:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:52:04

US3202395

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:41:52

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered 'Jan 1980'	System	02 Oct 2020 17:52:04

US3202395

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:41:52

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered '1980'	System	02 Oct 2020 17:52:04

US3202395

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered 'Jan 1980'	System	15 Oct 2020 14:35:45
User entered empty.	System	02 Oct 2020 17:52:04

US3202395

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered '1980'	System	15 Oct 2020 14:35:45
User entered empty.	System	02 Oct 2020 17:52:04

US3202395

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:41:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\23.0.	Coder Import (b) (4)	02 Oct 2020 17:54:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Oct 2020 17:54:50
Data point term sent to Coder	System	02 Oct 2020 17:54:07
User entered 'HYPOTHYROIDISM'	(b) (4), (b) (6)	02 Oct 2020 17:54:06

US3202395

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'UN UNK 1993'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:54:06

US3202395

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:41:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:54:06

US3202395

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:41:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:54:06

US3202395

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:54:06

US3202395

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:41:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:54:06

US3202395

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:41:52

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered 'Jan 1993'	System	02 Oct 2020 17:54:06

US3202395

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:41:52

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered '1993'	System	02 Oct 2020 17:54:06

US3202395

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered empty.	System	02 Oct 2020 17:54:06

US3202395

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered empty.	System	02 Oct 2020 17:54:06

US3202395

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:41:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User coded data point as SOC: Metabolism and nutrition disorders, HLT: Fat soluble vitamin deficiencies and disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\23.0.	Coder Import (b) (4)	02 Oct 2020 17:55:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Oct 2020 17:55:51
Data point term sent to Coder	System	02 Oct 2020 17:55:08
User entered 'VITAMIN D DEFICIENCY'	(b) (4), (b) (6)	02 Oct 2020 17:55:04

US3202395

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:55:04

US3202395

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:41:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:55:04

US3202395

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:41:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:55:04

US3202395

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:55:04

US3202395

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:41:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:55:04

US3202395

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:41:52

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered 'Jan 2010'	System	02 Oct 2020 17:55:04

US3202395

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:41:52

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered '2010'	System	02 Oct 2020 17:55:04

US3202395

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered empty.	System	02 Oct 2020 17:55:04

US3202395

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered empty.	System	02 Oct 2020 17:55:04

US3202395

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:41:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLG: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Basal cell carcinoma, LLT: Basal cell carcinoma - version MedDRA\23.0.	Coder Import (b) (4)	03 Oct 2020 08:47:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	03 Oct 2020 08:47:43
Data point term sent to Coder	System	02 Oct 2020 17:56:09
User entered 'LEFT BREAST BASAL CELL CANCER'	(b) (4), (b) (6)	02 Oct 2020 17:56:08

US3202395

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'UN UNK 1993'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:56:08

US3202395

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:41:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:56:08

US3202395

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:41:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:56:08

US3202395

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'UN UNK 1993'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:56:08

US3202395

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:41:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:56:08

US3202395

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:41:52

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered 'Jan 1993'	System	02 Oct 2020 17:56:08

US3202395

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:41:52

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered '1993'	System	02 Oct 2020 17:56:08

US3202395

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered 'Jan 1993'	System	02 Oct 2020 17:56:08

US3202395

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered '1993'	System	02 Oct 2020 17:56:08

US3202395

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:41:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User coded data point as SOC: Surgical and medical procedures, HLT: Mastectomies, PT: Breast conserving surgery, LLT: Lumpectomy - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 17:58:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 17:58:44
Data point term sent to Coder	System	02 Oct 2020 17:58:11
User entered 'LUMPECTOMY LEFT BREAST'	(b) (4), (b) (6)	02 Oct 2020 17:57:28

US3202395

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'UN UNK 1993'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:57:28

US3202395

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:41:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:57:28

US3202395

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:41:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:57:28

US3202395

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'UN UNK 1993'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:57:28

US3202395

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:41:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:57:28

US3202395

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:41:52

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered 'Jan 1993'	System	02 Oct 2020 17:57:28

US3202395

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:41:52

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered '1993'	System	02 Oct 2020 17:57:28

US3202395

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered 'Jan 1993'	System	02 Oct 2020 17:57:28

US3202395

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered '1993'	System	02 Oct 2020 17:57:28

US3202395

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:41:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal fusion surgery, LLT: Fusion lumbar spine - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 18:00:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 18:00:47
Data point term sent to Coder	System	02 Oct 2020 17:59:14
User entered 'LUMBAR FUSION'	(b) (4), (b) (6)	02 Oct 2020 17:58:14

US3202395

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'UN UNK 2009'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:58:14

US3202395

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:41:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:58:14

US3202395

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:41:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:58:14

US3202395

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'UN UNK 2009'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:58:14

US3202395

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:41:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:58:14

US3202395

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:41:52

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered 'Jan 2009'	System	02 Oct 2020 17:58:14

US3202395

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:41:52

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered '2009'	System	02 Oct 2020 17:58:14

US3202395

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered 'Jan 2009'	System	02 Oct 2020 17:58:14

US3202395

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered '2009'	System	02 Oct 2020 17:58:14

US3202395

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:41:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User coded data point as SOC: Nervous system disorders, HLGT: Spinal cord and nerve root disorders, HLT: Lumbar spinal cord and nerve root disorders, PT: Sciatica, LLT: Sciatica - version MedDRA\23.0.	Coder Import (b) (4)	02 Oct 2020 18:00:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Oct 2020 18:00:47
Data point term sent to Coder	System	02 Oct 2020 17:59:14
User entered 'SCIATIC NERVE PAIN'	(b) (4), (b) (6)	02 Oct 2020 17:59:08

US3202395

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'UN UNK 2000'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:59:08

US3202395

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:41:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:59:08

US3202395

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:41:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:59:08

US3202395

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:59:08

US3202395

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:41:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:59:08

US3202395

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:41:52

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered 'Jan 2000'	System	02 Oct 2020 17:59:08

US3202395

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:41:52

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered '2000'	System	02 Oct 2020 17:59:08

US3202395

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered empty.	System	02 Oct 2020 17:59:08

US3202395

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered empty.	System	02 Oct 2020 17:59:08

US3202395

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:41:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	(b) (4)	19 Jan 2021 22:06:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Jan 2021 22:06:10
Data point term sent to Coder	System	19 Jan 2021 22:05:10
User entered 'HYPERTENSION'	(b) (4), (b) (6)	19 Jan 2021 22:05:10

US3202395

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'UN UNK 2008'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 22:05:10

US3202395

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:41:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 22:05:10

US3202395

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:41:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 22:05:10

US3202395

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 22:05:10

US3202395

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:41:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 22:05:10

US3202395

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:41:52

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered 'Jan 2008'	System	19 Jan 2021 22:05:10

US3202395

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:41:52

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered '2008'	System	19 Jan 2021 22:05:10

US3202395

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered empty.	System	19 Jan 2021 22:05:10

US3202395

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered empty.	System	19 Jan 2021 22:05:10

US3202395

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:41:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\23.0.	Coder Import (b) (4)	24 Jan 2021 18:53:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	24 Jan 2021 18:53:51
Data point term sent to Coder	System	24 Jan 2021 18:53:36
User entered 'BACK PAIN'	(b) (4), (b) (6)	24 Jan 2021 18:52:47

US3202395

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'UN UNK 2008'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 18:52:47

US3202395

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:41:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 18:52:47

US3202395

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:41:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Jan 2021 18:53:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Jan 2021 18:53:17
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Jan 2021 18:53:17
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Jan 2021 18:52:47
User entered empty.	(b) (4), (b) (6)	24 Jan 2021 18:52:47

US3202395

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Jan 2021 18:52:47

US3202395

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:41:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 18:52:47

US3202395

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:41:52

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered 'Jan 2008'	System	24 Jan 2021 18:52:47

US3202395

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:41:52

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered '2008'	System	24 Jan 2021 18:52:47

US3202395

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered empty.	System	24 Jan 2021 18:52:47

US3202395

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered empty.	System	24 Jan 2021 18:52:47

US3202395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:09:57
	(b) (4)	

US3202395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '03 Sep 2020'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:09:57
	(b) (4)	

US3202395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '12:16'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:09:57
	(b) (4)	

US3202395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered '03 Sep 2020 12:16'	System	12 Sep 2020 16:09:57

US3202395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '159.0' cm	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:09:57
DataPoint set to visible.	(b) (4) System	03 Sep 2020 17:46:15

US3202395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '57.7' kg	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:09:57
DataPoint set to visible.	(b) (4) System	03 Sep 2020 17:46:15

US3202395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered '22.82346'	System	12 Sep 2020 16:09:57
DataPoint set to visible.	System	03 Sep 2020 17:46:15

US3202395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered 'kg/m2'	System	12 Sep 2020 16:09:57
DataPoint set to visible.	System	03 Sep 2020 17:46:15

US3202395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:09:57
	(b) (4)	

US3202395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered empty.	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:09:57
	(b) (4)	

US3202395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered empty.	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:09:57
	(b) (4)	

US3202395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:09:57

US3202395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered 'bpm'	System	12 Sep 2020 16:09:57

US3202395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:09:57

US3202395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered 'breaths/min'	System	12 Sep 2020 16:09:57

US3202395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:09:57

US3202395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered 'mmHg'	System	12 Sep 2020 16:09:57

US3202395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:09:57

US3202395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User entered 'mmHg'	System	12 Sep 2020 16:09:57

US3202395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29

US3202395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29

US3202395

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:52

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	04 Sep 2020 12:38:39

US3202395

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '3 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	04 Sep 2020 12:38:39

US3202395

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:41:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '03 Sep 2020'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:06:46
	(b) (4)	

US3202395

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:06:46
	(b) (4)	

US3202395

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User closed query 'Per DM CLR: Is the participant of childbearing potential? = NO: Surgically Sterile, however, the corresponding procedure is recorded as TUBAL LIGATION. Please confirm if this is Bilateral Tubal Ligation and update recorded procedure as appropriate, otherwise provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Nov 2020 16:27:16
User closed query 'Per CDM: 'Surgically Sterile' is recorded but there is no record of this on the Medical History form. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 16:22:25
Query 'Per DM CLR: Is the participant of childbearing potential? = NO: Surgically Sterile, however, the corresponding procedure is recorded as TUBAL LIGATION. Please confirm if this is Bilateral Tubal Ligation and update recorded procedure as appropriate, otherwise provide clarification.' answered with 'field updated' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	10 Oct 2020 19:58:12
User opened query 'Per DM CLR: Is the participant of childbearing potential? = NO: Surgically Sterile, however, the corresponding procedure is recorded as TUBAL LIGATION. Please confirm if this is Bilateral Tubal Ligation and update recorded procedure as appropriate, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 17:45:06
Query 'Per CDM: 'Surgically Sterile' is recorded but there is no record of this on the Medical History form. Please update accordingly.' answered with 'QUERY CORRECTED' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 18:47:05
User opened query 'Per CDM: 'Surgically Sterile' is recorded but there is no record of this on the Medical History form. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 13:21:01
User entered 'Surgically sterile (SURGICALLY STERILE)'	zackery harmon (b) (4) (b) (4)	12 Sep 2020 16:06:46

US3202395

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:41:52

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered empty.	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:06:46
	(b) (4)	

US3202395

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'un UNK 1980'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:06:46
	(b) (4)	

US3202395

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:41:52

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '0'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:06:46
	(b) (4)	

US3202395

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered empty.	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:06:46
	(b) (4)	

US3202395

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:41:52

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '0'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:06:46
	(b) (4)	

US3202395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:52

[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 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:08:47
	(b) (4)	

US3202395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:52

[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 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:08:47
	(b) (4)	

US3202395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:52

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 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:08:47
	(b) (4)	

US3202395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:52

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 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:08:47
	(b) (4)	

US3202395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:52

[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 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:08:47
	(b) (4)	

US3202395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:52

[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 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:08:47
	(b) (4)	

US3202395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:52

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 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:08:47
	(b) (4)	

US3202395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:52

[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 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:08:47
	(b) (4)	

US3202395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:52

[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 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:08:47
	(b) (4)	

US3202395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:52

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 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:08:47
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:52

[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 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:08:47
	(b) (4)	

US3202395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:52

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:08:47
	(b) (4)	

US3202395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:52

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered empty.	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:08:47
	(b) (4)	

US3202395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:52

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '0'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:08:47
	(b) (4)	

US3202395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '0'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:08:47
	(b) (4)	

US3202395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:52

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 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '0'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:08:47
	(b) (4)	

US3202395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:52

[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 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '0'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:08:47
	(b) (4)	

US3202395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:52

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 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '0'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:08:47

US3202395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '1'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:08:47

US3202395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:52

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '1'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:08:47

US3202395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:52

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:45:29
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'interacts in person with 5 or more people,	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:08:47

attended a large group event

plans on going to places where people gather

Husband is a professor at utc'

US3202395

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:41:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 29 SEP 2020 is reported under illness Visit Day 1 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) (4), (b) (6)	18 Nov 2020 06:59:04
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 29 SEP 2020 is reported under illness Visit Day 1 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 SAMPLE WAS COLLECTED ON VISIT ONE AND ANOTHER SAMPLE WAS COLLECTED ON THE SICK VISIT ON 29 SEP 2020' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 19:14:13
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 29 SEP 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 23:05:56
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	03 Sep 2020 17:46:26

US3202395

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:41:52

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '3 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 17:46:26

US3202395

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:41:52

[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 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Clinic (Clinic)'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 17:46:26

US3202395

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:41:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered 'VISIT1'	System	03 Sep 2020 17:46:26

US3202395

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '03 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 16:24:49

US3202395

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:41:52

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '189405'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 16:24:49

US3202395

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 16:24:49

US3202395

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:41:52

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 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 22:20:09

US3202395

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:41:52

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 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 22:20:09

US3202395

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:41:52

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 22:20:09

US3202395

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:41:52

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 22:20:09

US3202395

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:41:52

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 22:20:09

US3202395

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:41:52

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:43:43
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:12:07
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:12:06

US3202395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:41:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:11:20
	(b) (4)	

US3202395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:41:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:11:20
	(b) (4)	

US3202395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:41:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:11:20
	(b) (4)	

US3202395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:41:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:11:20
	(b) (4)	

US3202395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User accepted default value 'Pre-Dose (PREDOSE)'	zackery harmon (b) (4) (b) (4)	12 Sep 2020 16:11:20

US3202395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:11:20
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '03 Sep 2020'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:11:20
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '12:16'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:11:20

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered '03 Sep 2020 12:16'	System	12 Sep 2020 16:11:20

US3202395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '37.0' C	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:11:20
	(b) (4)	

US3202395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Oral (Oral)'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:11:20
	(b) (4)	

US3202395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered empty.	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:11:20
	(b) (4)	

US3202395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '68'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:11:20

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered 'bpm'	System	12 Sep 2020 16:11:20

US3202395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '16'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:11:20
	(b) (4)	

US3202395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered 'breaths/min'	System	12 Sep 2020 16:11:20

US3202395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '128'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:11:20

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered 'mmHg'	System	12 Sep 2020 16:11:20

US3202395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '79'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:11:20

US3202395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered 'mmHg'	System	12 Sep 2020 16:11:20

US3202395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:41:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:11:20
	(b) (4)	

US3202395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:41:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:11:20
	(b) (4)	

US3202395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User accepted default value 'Post-Dose (POSTDOSE)'	zackery harmon (b) (4) (b) (4)	12 Sep 2020 16:11:20

US3202395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:11:20
	(b) (4)	

US3202395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '03 Sep 2020'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:11:20
	(b) (4)	

US3202395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '13:57'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:11:20
	(b) (4)	

US3202395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered '03 Sep 2020 13:57'	System	12 Sep 2020 16:11:20

US3202395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '36.9' C	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:11:20
	(b) (4)	

US3202395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Oral (Oral)'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:11:20
	(b) (4)	

US3202395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered empty.	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:11:20
	(b) (4)	

US3202395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '64'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:11:20
	(b) (4)	

US3202395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered 'bpm'	System	12 Sep 2020 16:11:20

US3202395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '16'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:11:20
	(b) (4)	

US3202395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered 'breaths/min'	System	12 Sep 2020 16:11:20

US3202395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '132'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:11:20
	(b) (4)	

US3202395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered 'mmHg'	System	12 Sep 2020 16:11:20

US3202395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '85'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:11:20

US3202395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered 'mmHg'	System	12 Sep 2020 16:11:20

US3202395

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:52

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	04 Sep 2020 12:38:47

US3202395

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	04 Sep 2020 12:38:47

US3202395

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:41:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 17:46:50

US3202395

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:41:52

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 17:46:50

US3202395

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:41:52

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 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 17:46:50

US3202395

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:41:52

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 17:46:50

US3202395

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:41:52

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '3 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 17:46:50

US3202395

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '13:22'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 17:46:50

US3202395

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered '3 Sep 2020 13:22'	System	03 Sep 2020 17:46:50

US3202395

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 17:46:50

US3202395

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered 'ONCE'	System	03 Sep 2020 17:46:50

US3202395

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 17:46:50

US3202395

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	04 Sep 2020 12:42:56

US3202395

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:52

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '3 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	04 Sep 2020 12:42:56

US3202395

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:52

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '12:48'	(b) (4) Tiffany Jewell (b) (4)	04 Sep 2020 12:42:56

US3202395

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered '3 Sep 2020 12:48'	System	04 Sep 2020 12:42:56

US3202395

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:41:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '3 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	04 Sep 2020 16:13:19

US3202395

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:41:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tiffany Jewell (b) (4) (b) (4)	04 Sep 2020 16:13:19

US3202395

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:41:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	04 Sep 2020 16:13:19

US3202395

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:41:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '12:24'	(b) (4) Tiffany Jewell (b) (4)	04 Sep 2020 16:13:19

US3202395

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered '3 Sep 2020 12:24'	System	04 Sep 2020 16:13:19

US3202395

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:41:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tiffany Jewell (b) (4) (b) (4)	04 Sep 2020 16:13:19

US3202395

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:41:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	04 Sep 2020 16:13:19

US3202395

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:41:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	04 Sep 2020 16:13:19

US3202395

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered empty.	System	04 Sep 2020 16:13:19

US3202395

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	04 Sep 2020 12:43:01

US3202395

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:41:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered '1'	System	04 Sep 2020 12:43:01

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	03 Sep 2020 17:46:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-03T13:56:22', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '65798ccf-a7cf-4cb0-9d24-1b62bc138dd4'	System	03 Sep 2020 17:57:08
User entered 'Yes (Y)'	System	03 Sep 2020 17:57:08

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-03T13:56:29', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '65798ccf-a7cf-4cb0-9d24-1b62bc138dd4'	System	03 Sep 2020 17:57:08
User entered '98.5'	System	03 Sep 2020 17:57:08

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-03T13:56:52', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '65798ccf-a7cf-4cb0-9d24-1b62bc138dd4'	System	03 Sep 2020 17:57:08
User entered 'No (N)'	System	03 Sep 2020 17:57:08

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-03T13:57:04', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '65798ccf-a7cf-4cb0-9d24-1b62bc138dd4'	System	03 Sep 2020 17:57:08
User entered '03 Sep 2020 13:57'	System	03 Sep 2020 17:57:08

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '03 Sep 2020 13:42'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '03 Sep 2020 16:12'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	03 Sep 2020 17:46:50
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-03T21:23:14', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'ae0ebf79-41ba-4754-a857-68e8e303c7fe'	System	04 Sep 2020 01:23:36
User entered 'Yes (Y)'	System	04 Sep 2020 01:23:36

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-03T21:23:22', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'ae0ebf79-41ba-4754-a857-68e8e303c7fe'	System	04 Sep 2020 01:23:36
User entered '98.6'	System	04 Sep 2020 01:23:36

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-03T21:23:25', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'ae0ebf79-41ba-4754-a857-68e8e303c7fe'	System	04 Sep 2020 01:23:36
User entered 'No (N)'	System	04 Sep 2020 01:23:36

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-03T21:23:32', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'ae0ebf79-41ba-4754-a857-68e8e303c7fe'	System	04 Sep 2020 01:23:36
User entered '03 Sep 2020 21:23'	System	04 Sep 2020 01:23:36

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '03 Sep 2020 17:07'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	03 Sep 2020 17:46:50
User entered 'Day 2'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-04T20:41:05', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '06fa8a1f-e766-4bad-a3f6-5bb9739fb633'	System	05 Sep 2020 00:41:39
User entered 'Yes (Y)'	System	05 Sep 2020 00:41:39

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-04T20:41:22', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '06fa8a1f-e766-4bad-a3f6-5bb9739fb633'	System	05 Sep 2020 00:41:39
User entered '98.2'	System	05 Sep 2020 00:41:39

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-04T20:41:28', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '06fa8a1f-e766-4bad-a3f6-5bb9739fb633'	System	05 Sep 2020 00:41:39
User entered 'No (N)'	System	05 Sep 2020 00:41:39

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-04T20:41:35', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '06fa8a1f-e766-4bad-a3f6-5bb9739fb633'	System	05 Sep 2020 00:41:39
User entered '04 Sep 2020 20:41'	System	05 Sep 2020 00:41:39

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	03 Sep 2020 17:46:50
User entered 'Day 3'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-05T21:44:39', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'efc2a618-c853-4357-9f1c-3dede283a08c'	System	06 Sep 2020 01:46:12
User entered 'Yes (Y)'	System	06 Sep 2020 01:46:12

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-05T21:45:47', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'efc2a618-c853-4357-9f1c-3dede283a08c'	System	06 Sep 2020 01:46:12
User entered '97.3'	System	06 Sep 2020 01:46:12

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-05T21:46:05', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'efc2a618-c853-4357-9f1c-3dede283a08c'	System	06 Sep 2020 01:46:12
User entered 'No (N)'	System	06 Sep 2020 01:46:12

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-05T21:46:09', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'efc2a618-c853-4357-9f1c-3dede283a08c'	System	06 Sep 2020 01:46:12
User entered '05 Sep 2020 21:46'	System	06 Sep 2020 01:46:12

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	03 Sep 2020 17:46:50
User entered 'Day 4'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-06T21:45:32', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '2b66039b-b1a5-4167-b3c4-847281088230'	System	07 Sep 2020 01:46:17
User entered 'Yes (Y)'	System	07 Sep 2020 01:46:17

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-06T21:46:05', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '2b66039b-b1a5-4167-b3c4-847281088230'	System	07 Sep 2020 01:46:17
User entered '98.2'	System	07 Sep 2020 01:46:17

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-06T21:46:08', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '2b66039b-b1a5-4167-b3c4-847281088230'	System	07 Sep 2020 01:46:17
User entered 'No (N)'	System	07 Sep 2020 01:46:17

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-06T21:46:13', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '2b66039b-b1a5-4167-b3c4-847281088230'	System	07 Sep 2020 01:46:17
User entered '06 Sep 2020 21:46'	System	07 Sep 2020 01:46:17

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	03 Sep 2020 17:46:50
User entered 'Day 5'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-07T20:12:56', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '30bc803f-804f-4903-b130-2f49638215b5'	System	08 Sep 2020 00:13:17
User entered 'Yes (Y)'	System	08 Sep 2020 00:13:17

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-07T20:13:05', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '30bc803f-804f-4903-b130-2f49638215b5'	System	08 Sep 2020 00:13:17
User entered '98.4'	System	08 Sep 2020 00:13:17

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-07T20:13:08', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '30bc803f-804f-4903-b130-2f49638215b5'	System	08 Sep 2020 00:13:17
User entered 'No (N)'	System	08 Sep 2020 00:13:17

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-07T20:13:13', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '30bc803f-804f-4903-b130-2f49638215b5'	System	08 Sep 2020 00:13:17
User entered '07 Sep 2020 20:13'	System	08 Sep 2020 00:13:17

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	03 Sep 2020 17:46:50
User entered 'Day 6'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-08T21:25:54', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '253ce592-29f1-4fe7-990c-d0a9bcaf6865'	System	09 Sep 2020 01:26:17
User entered 'Yes (Y)'	System	09 Sep 2020 01:26:17

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-08T21:26:04', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '253ce592-29f1-4fe7-990c-d0a9bcaf6865'	System	09 Sep 2020 01:26:17
User entered '97.6'	System	09 Sep 2020 01:26:17

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-08T21:26:07', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '253ce592-29f1-4fe7-990c-d0a9bc6f6865'	System	09 Sep 2020 01:26:17
User entered 'No (N)'	System	09 Sep 2020 01:26:17

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-08T21:26:11', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '253ce592-29f1-4fe7-990c-d0a9bc6f6865'	System	09 Sep 2020 01:26:17
User entered '08 Sep 2020 21:26'	System	09 Sep 2020 01:26:17

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	03 Sep 2020 17:46:50
User entered 'Day 7'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-09T21:14:22', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '7cb8496a-2705-44cd-91e1-624f52ad1208'	System	10 Sep 2020 01:14:43
User entered 'Yes (Y)'	System	10 Sep 2020 01:14:43

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-09T21:14:30', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '7cb8496a-2705-44cd-91e1-624f52ad1208'	System	10 Sep 2020 01:14:43
User entered '97.7'	System	10 Sep 2020 01:14:43

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-09T21:14:33', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '7cb8496a-2705-44cd-91e1-624f52ad1208'	System	10 Sep 2020 01:14:43
User entered 'No (N)'	System	10 Sep 2020 01:14:43

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-09T21:14:39', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '7cb8496a-2705-44cd-91e1-624f52ad1208'	System	10 Sep 2020 01:14:43
User entered '09 Sep 2020 21:14'	System	10 Sep 2020 01:14:43

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	03 Sep 2020 17:46:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-03T13:57:22', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '05a1f78b-a008-4b81-bdf5-01adf268490e'	System	03 Sep 2020 17:58:17
User entered 'None (1)'	System	03 Sep 2020 17:58:17

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-03T13:57:44', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '05a1f78b-a008-4b81-bdf5-01adf268490e'	System	03 Sep 2020 17:58:17
User entered 'No (N)'	System	03 Sep 2020 17:58:17

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-03T13:57:48', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '05a1f78b-a008-4b81-bdf5-01adf268490e'	System	03 Sep 2020 17:58:17
User entered 'No (N)'	System	03 Sep 2020 17:58:17

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-03T13:58:02', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '05a1f78b-a008-4b81-bdf5-01adf268490e'	System	03 Sep 2020 17:58:17
User entered 'None (1)'	System	03 Sep 2020 17:58:17

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-03T13:58:10', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '05a1f78b-a008-4b81-bdf5-01adf268490e'	System	03 Sep 2020 17:58:17
User entered '03 Sep 2020 13:58'	System	03 Sep 2020 17:58:17

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '03 Sep 2020 13:42'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '03 Sep 2020 16:12'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	03 Sep 2020 17:46:50
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-03T21:24:15', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'dccb00a9-449b-4dc4-94b8-84ed88eeeb7'	System	04 Sep 2020 01:24:38
User entered 'None (1)'	System	04 Sep 2020 01:24:38

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-03T21:24:19', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'dccb00a9-449b-4dc4-94b8-84ed88eeeb7'	System	04 Sep 2020 01:24:38
User entered 'No (N)'	System	04 Sep 2020 01:24:38

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-03T21:24:23', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'dccb00a9-449b-4dc4-94b8-84ed88eeeb7'	System	04 Sep 2020 01:24:38
User entered 'No (N)'	System	04 Sep 2020 01:24:38

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-03T21:24:27', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'dccb00a9-449b-4dc4-94b8-84ed88eeeb7'	System	04 Sep 2020 01:24:38
User entered 'None (1)'	System	04 Sep 2020 01:24:38

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-03T21:24:34', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'dccb00a9-449b-4dc4-94b8-84ed88eeeb7'	System	04 Sep 2020 01:24:38
User entered '03 Sep 2020 21:24'	System	04 Sep 2020 01:24:38

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '03 Sep 2020 17:07'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	03 Sep 2020 17:46:50
User entered 'Day 2'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-04T20:41:42', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'c44c7344-f1d8-4f4e-9275-ada464e24ac3'	System	05 Sep 2020 00:42:00
User entered 'None (1)'	System	05 Sep 2020 00:42:00

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-04T20:41:45', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'c44c7344-f1d8-4f4e-9275-ada464e24ac3'	System	05 Sep 2020 00:42:00
User entered 'No (N)'	System	05 Sep 2020 00:42:00

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-04T20:41:48', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'c44c7344-f1d8-4f4e-9275-ada464e24ac3'	System	05 Sep 2020 00:42:00
User entered 'No (N)'	System	05 Sep 2020 00:42:00

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-04T20:41:52', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'c44c7344-f1d8-4f4e-9275-ada464e24ac3'	System	05 Sep 2020 00:42:00
User entered 'None (1)'	System	05 Sep 2020 00:42:00

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-04T20:41:58', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'c44c7344-f1d8-4f4e-9275-ada464e24ac3'	System	05 Sep 2020 00:42:00
User entered '04 Sep 2020 20:41'	System	05 Sep 2020 00:42:00

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	03 Sep 2020 17:46:50
User entered 'Day 3'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-05T21:46:16', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '851d2da5-bdfa-4067-8415-aaf1f6a3aa00'	System	06 Sep 2020 01:46:34
User entered 'None (1)'	System	06 Sep 2020 01:46:34

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-05T21:46:19', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '851d2da5-bdfa-4067-8415-aaf1f6a3aa00'	System	06 Sep 2020 01:46:34
User entered 'No (N)'	System	06 Sep 2020 01:46:34

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-05T21:46:22', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '851d2da5-bdfa-4067-8415-aaf1f6a3aa00'	System	06 Sep 2020 01:46:34
User entered 'No (N)'	System	06 Sep 2020 01:46:34

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-05T21:46:25', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '851d2da5-bdfa-4067-8415-aaf1f6a3aa00'	System	06 Sep 2020 01:46:34
User entered 'None (1)'	System	06 Sep 2020 01:46:34

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-05T21:46:29', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '851d2da5-bdfa-4067-8415-aaf1f6a3aa00'	System	06 Sep 2020 01:46:34
User entered '05 Sep 2020 21:46'	System	06 Sep 2020 01:46:34

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	03 Sep 2020 17:46:50
User entered 'Day 4'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-06T21:46:19', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '81181e99-1753-4bd3-838c-e9683904b2d8'	System	07 Sep 2020 01:46:37
User entered 'None (1)'	System	07 Sep 2020 01:46:37

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-06T21:46:22', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '81181e99-1753-4bd3-838c-e9683904b2d8'	System	07 Sep 2020 01:46:37
User entered 'No (N)'	System	07 Sep 2020 01:46:37

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-06T21:46:25', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '81181e99-1753-4bd3-838c-e9683904b2d8'	System	07 Sep 2020 01:46:37
User entered 'No (N)'	System	07 Sep 2020 01:46:37

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-06T21:46:28', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '81181e99-1753-4bd3-838c-e9683904b2d8'	System	07 Sep 2020 01:46:37
User entered 'None (1)'	System	07 Sep 2020 01:46:37

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-06T21:46:35', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '81181e99-1753-4bd3-838c-e9683904b2d8'	System	07 Sep 2020 01:46:37
User entered '06 Sep 2020 21:46'	System	07 Sep 2020 01:46:37

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	03 Sep 2020 17:46:50
User entered 'Day 5'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-07T20:13:18', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'ce967047-3e77-4cbe-9fac-bc7064c4435c'	System	08 Sep 2020 00:13:34
User entered 'None (1)'	System	08 Sep 2020 00:13:34

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-07T20:13:21', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'ce967047-3e77-4cbe-9fac-bc7064c4435c'	System	08 Sep 2020 00:13:34
User entered 'No (N)'	System	08 Sep 2020 00:13:34

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-07T20:13:24', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'ce967047-3e77-4cbe-9fac-bc7064c4435c'	System	08 Sep 2020 00:13:34
User entered 'No (N)'	System	08 Sep 2020 00:13:34

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-07T20:13:26', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'ce967047-3e77-4cbe-9fac-bc7064c4435c'	System	08 Sep 2020 00:13:34
User entered 'None (1)'	System	08 Sep 2020 00:13:34

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-07T20:13:30', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'ce967047-3e77-4cbe-9fac-bc7064c4435c'	System	08 Sep 2020 00:13:34
User entered '07 Sep 2020 20:13'	System	08 Sep 2020 00:13:34

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	03 Sep 2020 17:46:50
User entered 'Day 6'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-08T21:26:16', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '82969a72-4edb-4460-a941-c19950b0536f'	System	09 Sep 2020 01:26:32
User entered 'None (1)'	System	09 Sep 2020 01:26:32

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-08T21:26:19', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '82969a72-4edb-4460-a941-c19950b0536f'	System	09 Sep 2020 01:26:32
User entered 'No (N)'	System	09 Sep 2020 01:26:32

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-08T21:26:21', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '82969a72-4edb-4460-a941-c19950b0536f'	System	09 Sep 2020 01:26:32
User entered 'No (N)'	System	09 Sep 2020 01:26:32

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-08T21:26:24', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '82969a72-4edb-4460-a941-c19950b0536f'	System	09 Sep 2020 01:26:32
User entered 'None (1)'	System	09 Sep 2020 01:26:32

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-08T21:26:28', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '82969a72-4edb-4460-a941-c19950b0536f' User entered '08 Sep 2020 21:26'	System	09 Sep 2020 01:26:32
	System	09 Sep 2020 01:26:32

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	03 Sep 2020 17:46:50
User entered 'Day 7'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-09T21:14:43', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '0d77b92e-ce8e-4559-9b05-02aad2a8e4e3'	System	10 Sep 2020 01:14:57
User entered 'None (1)'	System	10 Sep 2020 01:14:57

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-09T21:14:45', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '0d77b92e-ce8e-4559-9b05-02aad2a8e4e3'	System	10 Sep 2020 01:14:57
User entered 'No (N)'	System	10 Sep 2020 01:14:57

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-09T21:14:48', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '0d77b92e-ce8e-4559-9b05-02aad2a8e4e3'	System	10 Sep 2020 01:14:57
User entered 'No (N)'	System	10 Sep 2020 01:14:57

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-09T21:14:50', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '0d77b92e-ce8e-4559-9b05-02aad2a8e4e3'	System	10 Sep 2020 01:14:57
User entered 'None (1)'	System	10 Sep 2020 01:14:57

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-09T21:14:53', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '0d77b92e-ce8e-4559-9b05-02aad2a8e4e3'	System	10 Sep 2020 01:14:57
User entered '09 Sep 2020 21:14'	System	10 Sep 2020 01:14:57

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	03 Sep 2020 17:46:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-03T13:58:21', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '40014845-7fa1-4aa4-9cf1-00e5f6031d88'	System	03 Sep 2020 17:59:04
User entered 'None (0)'	System	03 Sep 2020 17:59:04

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-03T13:58:28', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '40014845-7fa1-4aa4-9cf1-00e5f6031d88'	System	03 Sep 2020 17:59:04
User entered 'None (0)'	System	03 Sep 2020 17:59:04

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-03T13:58:31', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '40014845-7fa1-4aa4-9cf1-00e5f6031d88'	System	03 Sep 2020 17:59:04
User entered 'None (0)'	System	03 Sep 2020 17:59:04

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-03T13:58:35', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '40014845-7fa1-4aa4-9cf1-00e5f6031d88'	System	03 Sep 2020 17:59:04
User entered 'None (0)'	System	03 Sep 2020 17:59:04

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-03T13:58:40', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '40014845-7fa1-4aa4-9cf1-00e5f6031d88'	System	03 Sep 2020 17:59:04
User entered 'None (0)'	System	03 Sep 2020 17:59:04

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-03T13:58:43', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '40014845-7fa1-4aa4-9cf1-00e5f6031d88'	System	03 Sep 2020 17:59:04
User entered 'None (0)'	System	03 Sep 2020 17:59:04

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-03T13:58:51', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '40014845-7fa1-4aa4-9cf1-00e5f6031d88'	System	03 Sep 2020 17:59:04
User entered 'No (N)'	System	03 Sep 2020 17:59:04

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-03T13:58:59', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '40014845-7fa1-4aa4-9cf1-00e5f6031d88'	System	03 Sep 2020 17:59:04
User entered '03 Sep 2020 13:58'	System	03 Sep 2020 17:59:04

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '03 Sep 2020 13:42'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '03 Sep 2020 16:12'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	03 Sep 2020 17:46:50
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-03T21:24:41', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '2fca3a91-78c6-4970-939d-9bf216259537'	System	04 Sep 2020 01:25:20
User entered 'None (0)'	System	04 Sep 2020 01:25:20

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bf0fab6f)', Time: '2020-09-03T21:24:45', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '2fca3a91-78c6-4970-939d-9bf216259537'	System	04 Sep 2020 01:25:20
User entered 'None (0)'	System	04 Sep 2020 01:25:20

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-03T21:24:49', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '2fca3a91-78c6-4970-939d-9bf216259537'	System	04 Sep 2020 01:25:20
User entered 'None (0)'	System	04 Sep 2020 01:25:20

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-03T21:24:54', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '2fca3a91-78c6-4970-939d-9bf216259537'	System	04 Sep 2020 01:25:20
User entered 'None (0)'	System	04 Sep 2020 01:25:20

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-03T21:24:58', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '2fca3a91-78c6-4970-939d-9bf216259537'	System	04 Sep 2020 01:25:20
User entered 'None (0)'	System	04 Sep 2020 01:25:20

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-03T21:25:01', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '2fca3a91-78c6-4970-939d-9bf216259537'	System	04 Sep 2020 01:25:20
User entered 'None (0)'	System	04 Sep 2020 01:25:20

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-03T21:25:07', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '2fca3a91-78c6-4970-939d-9bf216259537'	System	04 Sep 2020 01:25:20
User entered 'No (N)'	System	04 Sep 2020 01:25:20

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-03T21:25:16', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '2fca3a91-78c6-4970-939d-9bf216259537'	System	04 Sep 2020 01:25:20
User entered '03 Sep 2020 21:25'	System	04 Sep 2020 01:25:20

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '03 Sep 2020 17:07'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	03 Sep 2020 17:46:50
User entered 'Day 2'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-04T20:42:04', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '86427d68-8dc2-4e4a-b99e-4c00ce6d7257'	System	05 Sep 2020 00:42:42
User entered 'None (0)'	System	05 Sep 2020 00:42:42

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-04T20:42:09', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '86427d68-8dc2-4e4a-b99e-4c00ce6d7257'	System	05 Sep 2020 00:42:42
User entered 'None (0)'	System	05 Sep 2020 00:42:42

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bf0fab6f)', Time: '2020-09-04T20:42:13', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '86427d68-8dc2-4e4a-b99e-4c00ce6d7257'	System	05 Sep 2020 00:42:42
User entered 'None (0)'	System	05 Sep 2020 00:42:42

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bf0fab6f)', Time: '2020-09-04T20:42:18', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '86427d68-8dc2-4e4a-b99e-4c00ce6d7257'	System	05 Sep 2020 00:42:42
User entered 'None (0)'	System	05 Sep 2020 00:42:42

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-04T20:42:22', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '86427d68-8dc2-4e4a-b99e-4c00ce6d7257'	System	05 Sep 2020 00:42:42
User entered 'None (0)'	System	05 Sep 2020 00:42:42

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-04T20:42:25', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '86427d68-8dc2-4e4a-b99e-4c00ce6d7257'	System	05 Sep 2020 00:42:42
User entered 'None (0)'	System	05 Sep 2020 00:42:42

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bf0fab6f)', Time: '2020-09-04T20:42:31', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '86427d68-8dc2-4e4a-b99e-4c00ce6d7257'	System	05 Sep 2020 00:42:42
User entered 'No (N)'	System	05 Sep 2020 00:42:42

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-04T20:42:39', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '86427d68-8dc2-4e4a-b99e-4c00ce6d7257'	System	05 Sep 2020 00:42:42
User entered '04 Sep 2020 20:42'	System	05 Sep 2020 00:42:42

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	03 Sep 2020 17:46:50
User entered 'Day 3'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-05T21:46:33', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'e914dd32-b900-46cb-b5b0-2b5e937aa268'	System	06 Sep 2020 01:46:58
User entered 'None (0)'	System	06 Sep 2020 01:46:58

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-05T21:46:36', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'e914dd32-b900-46cb-b5b0-2b5e937aa268'	System	06 Sep 2020 01:46:58
User entered 'None (0)'	System	06 Sep 2020 01:46:58

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-05T21:46:39', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'e914dd32-b900-46cb-b5b0-2b5e937aa268'	System	06 Sep 2020 01:46:58
User entered 'None (0)'	System	06 Sep 2020 01:46:58

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-05T21:46:42', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'e914dd32-b900-46cb-b5b0-2b5e937aa268'	System	06 Sep 2020 01:46:58
User entered 'None (0)'	System	06 Sep 2020 01:46:58

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-05T21:46:45', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'e914dd32-b900-46cb-b5b0-2b5e937aa268'	System	06 Sep 2020 01:46:58
User entered 'None (0)'	System	06 Sep 2020 01:46:58

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-05T21:46:49', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'e914dd32-b900-46cb-b5b0-2b5e937aa268'	System	06 Sep 2020 01:46:58
User entered 'None (0)'	System	06 Sep 2020 01:46:58

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-05T21:46:52', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'e914dd32-b900-46cb-b5b0-2b5e937aa268'	System	06 Sep 2020 01:46:58
User entered 'No (N)'	System	06 Sep 2020 01:46:58

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-05T21:46:55', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'e914dd32-b900-46cb-b5b0-2b5e937aa268'	System	06 Sep 2020 01:46:58
User entered '05 Sep 2020 21:46'	System	06 Sep 2020 01:46:58

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	03 Sep 2020 17:46:50
User entered 'Day 4'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-06T21:46:40', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'f9724d59-8d07-4325-9f44-bd3e5f2250c7'	System	07 Sep 2020 01:47:01
User entered 'None (0)'	System	07 Sep 2020 01:47:01

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-06T21:46:42', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'f9724d59-8d07-4325-9f44-bd3e5f2250c7'	System	07 Sep 2020 01:47:01
User entered 'None (0)'	System	07 Sep 2020 01:47:01

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-06T21:46:45', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'f9724d59-8d07-4325-9f44-bd3e5f2250c7'	System	07 Sep 2020 01:47:01
User entered 'None (0)'	System	07 Sep 2020 01:47:01

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-06T21:46:47', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'f9724d59-8d07-4325-9f44-bd3e5f2250c7'	System	07 Sep 2020 01:47:01
User entered 'None (0)'	System	07 Sep 2020 01:47:01

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-06T21:46:50', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'f9724d59-8d07-4325-9f44-bd3e5f2250c7'	System	07 Sep 2020 01:47:01
User entered 'None (0)'	System	07 Sep 2020 01:47:01

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-06T21:46:52', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'f9724d59-8d07-4325-9f44-bd3e5f2250c7'	System	07 Sep 2020 01:47:01
User entered 'None (0)'	System	07 Sep 2020 01:47:01

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-06T21:46:55', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'f9724d59-8d07-4325-9f44-bd3e5f2250c7'	System	07 Sep 2020 01:47:01
User entered 'No (N)'	System	07 Sep 2020 01:47:01

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-06T21:46:59', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'f9724d59-8d07-4325-9f44-bd3e5f2250c7'	System	07 Sep 2020 01:47:01
User entered '06 Sep 2020 21:46'	System	07 Sep 2020 01:47:01

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	03 Sep 2020 17:46:50
User entered 'Day 5'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-07T20:13:35', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '60a68eae-d51b-4aec-a514-df42de04e426'	System	08 Sep 2020 00:13:53
User entered 'None (0)'	System	08 Sep 2020 00:13:53

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-07T20:13:38', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '60a68eae-d51b-4aec-a514-df42de04e426'	System	08 Sep 2020 00:13:53
User entered 'None (0)'	System	08 Sep 2020 00:13:53

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-07T20:13:39', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '60a68eae-d51b-4aec-a514-df42de04e426'	System	08 Sep 2020 00:13:53
User entered 'None (0)'	System	08 Sep 2020 00:13:53

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-07T20:13:41', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '60a68eae-d51b-4aec-a514-df42de04e426'	System	08 Sep 2020 00:13:53
User entered 'None (0)'	System	08 Sep 2020 00:13:53

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-07T20:13:44', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '60a68eae-d51b-4aec-a514-df42de04e426'	System	08 Sep 2020 00:13:53
User entered 'None (0)'	System	08 Sep 2020 00:13:53

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-07T20:13:46', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '60a68eae-d51b-4aec-a514-df42de04e426'	System	08 Sep 2020 00:13:53
User entered 'None (0)'	System	08 Sep 2020 00:13:53

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-07T20:13:48', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '60a68eae-d51b-4aec-a514-df42de04e426'	System	08 Sep 2020 00:13:53
User entered 'No (N)'	System	08 Sep 2020 00:13:53

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-07T20:13:51', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '60a68eae-d51b-4aec-a514-df42de04e426'	System	08 Sep 2020 00:13:53
User entered '07 Sep 2020 20:13'	System	08 Sep 2020 00:13:53

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	03 Sep 2020 17:46:50
User entered 'Day 6'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-08T21:26:32', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '0d333c1f-a640-4b4f-946c-e1745c4f27ef'	System	09 Sep 2020 01:26:54
User entered 'None (0)'	System	09 Sep 2020 01:26:54

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-08T21:26:34', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '0d333c1f-a640-4b4f-946c-e1745c4f27ef'	System	09 Sep 2020 01:26:54
User entered 'None (0)'	System	09 Sep 2020 01:26:54

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-08T21:26:36', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '0d333c1f-a640-4b4f-946c-e1745c4f27ef'	System	09 Sep 2020 01:26:54
User entered 'None (0)'	System	09 Sep 2020 01:26:54

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-08T21:26:38', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '0d333c1f-a640-4b4f-946c-e1745c4f27ef'	System	09 Sep 2020 01:26:54
User entered 'None (0)'	System	09 Sep 2020 01:26:54

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-08T21:26:42', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '0d333c1f-a640-4b4f-946c-e1745c4f27ef'	System	09 Sep 2020 01:26:54
User entered 'None (0)'	System	09 Sep 2020 01:26:54

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-08T21:26:44', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '0d333c1f-a640-4b4f-946c-e1745c4f27ef'	System	09 Sep 2020 01:26:54
User entered 'None (0)'	System	09 Sep 2020 01:26:54

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-08T21:26:47', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '0d333c1f-a640-4b4f-946c-e1745c4f27ef'	System	09 Sep 2020 01:26:54
User entered 'No (N)'	System	09 Sep 2020 01:26:54

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-08T21:26:50', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '0d333c1f-a640-4b4f-946c-e1745c4f27ef' User entered '08 Sep 2020 21:26'	System	09 Sep 2020 01:26:54
	System	09 Sep 2020 01:26:54

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	03 Sep 2020 17:46:50
User entered 'Day 7'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-09T21:14:58', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'a031162f-734d-4c56-83bb-20d4d1185386'	System	10 Sep 2020 01:15:19
User entered 'None (0)'	System	10 Sep 2020 01:15:19

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-09T21:15:00', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'a031162f-734d-4c56-83bb-20d4d1185386'	System	10 Sep 2020 01:15:19
User entered 'None (0)'	System	10 Sep 2020 01:15:19

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-09T21:15:02', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'a031162f-734d-4c56-83bb-20d4d1185386'	System	10 Sep 2020 01:15:19
User entered 'None (0)'	System	10 Sep 2020 01:15:19

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-09T21:15:04', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'a031162f-734d-4c56-83bb-20d4d1185386'	System	10 Sep 2020 01:15:19
User entered 'None (0)'	System	10 Sep 2020 01:15:19

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-09T21:15:06', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'a031162f-734d-4c56-83bb-20d4d1185386'	System	10 Sep 2020 01:15:19
User entered 'None (0)'	System	10 Sep 2020 01:15:19

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-09T21:15:08', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'a031162f-734d-4c56-83bb-20d4d1185386'	System	10 Sep 2020 01:15:19
User entered 'None (0)'	System	10 Sep 2020 01:15:19

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-09T21:15:11', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'a031162f-734d-4c56-83bb-20d4d1185386'	System	10 Sep 2020 01:15:19
User entered 'No (N)'	System	10 Sep 2020 01:15:19

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-09-09T21:15:14', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'a031162f-734d-4c56-83bb-20d4d1185386'	System	10 Sep 2020 01:15:19
User entered '09 Sep 2020 21:15'	System	10 Sep 2020 01:15:19

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 17:46:50

US3202395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 17:46:50

US3202395

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	18 Sep 2020 15:51:38
	(b) (4)	

US3202395

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '10 Sep 2020'	Lilian Nukuna (b) (4)	18 Sep 2020 15:51:38

US3202395

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lilian Nukuna (b) (4)	18 Sep 2020 15:51:38

US3202395

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered empty.	(b) (4) Lilian Nukuna (b) (4)	18 Sep 2020 15:51:38
	(b) (4)	

US3202395

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Yes (Y)'	Lilian Nukuna (b) (4)	18 Sep 2020 15:51:45

US3202395

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered '1'	System	18 Sep 2020 15:51:45

US3202395

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	18 Sep 2020 15:51:58
	(b) (4)	

US3202395

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '18 Sep 2020'	Lilian Nukuna (b) (4)	18 Sep 2020 15:51:58

US3202395

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4)	18 Sep 2020 15:51:58

US3202395

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered empty.	(b) (4) Lilian Nukuna (b) (4)	18 Sep 2020 15:51:58
	(b) (4)	

US3202395

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	18 Sep 2020 15:52:03
	(b) (4)	

US3202395

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered '1'	System	18 Sep 2020 15:52:03

US3202395

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	24 Sep 2020 14:56:35
	(b) (4)	

US3202395

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '24 Sep 2020'	(b) (4) Lilian Nukuna (b) (4)	24 Sep 2020 14:56:35
	(b) (4)	

US3202395

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4)	24 Sep 2020 14:56:35

US3202395

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered empty.	(b) (4) Lilian Nukuna (b) (4)	24 Sep 2020 14:56:35
	(b) (4)	

US3202395

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Yes (Y)'	Lilian Nukuna (b) (4)	24 Sep 2020 14:56:48

US3202395

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered '1'	System	24 Sep 2020 14:56:48

US3202395

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	07 Oct 2020 16:07:40

US3202395

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '7 Oct 2020'	(b) (4) Tiffany Jewell (b) (4)	07 Oct 2020 16:07:40

US3202395

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:52

[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 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Clinic (Clinic)'	(b) (4) Tiffany Jewell (b) (4)	07 Oct 2020 16:07:40

US3202395

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered 'VISIT2'	System	07 Oct 2020 16:07:40

US3202395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User accepted default value 'Pre-Dose (PREDOSE)'	Teresa Deese (b) (4)	14 Oct 2020 14:48:16

US3202395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:43
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 14:48:16

US3202395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:43
User entered '07 Oct 2020'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 14:48:16

US3202395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:43
User entered '11:03'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 14:48:16

US3202395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered '07 Oct 2020 11:03'	System	14 Oct 2020 14:48:16

US3202395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:43
User entered '36.8' C	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 14:48:16

US3202395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:43
User entered 'Oral (Oral)'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 14:48:16

US3202395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:43
User entered empty.	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 14:48:16

US3202395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:43
User entered '66'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 14:48:16

US3202395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered 'bpm'	System	14 Oct 2020 14:48:16

US3202395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:43
User entered '18'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 14:48:16

US3202395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered 'breaths/min'	System	14 Oct 2020 14:48:16

US3202395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:43
User entered '123'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 14:48:16

US3202395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered 'mmHg'	System	14 Oct 2020 14:48:16

US3202395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:43
User entered '79'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 14:48:16

US3202395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered 'mmHg'	System	14 Oct 2020 14:48:16

US3202395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User accepted default value 'Post-Dose (POSTDOSE)'	Teresa Deese (b) (4)	14 Oct 2020 14:48:16

US3202395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:43
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 14:48:16

US3202395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:43
User entered '07 Oct 2020'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 14:48:16

US3202395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:43
User entered '12:17'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 14:48:16

US3202395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered '07 Oct 2020 12:17'	System	14 Oct 2020 14:48:16

US3202395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:43
User entered '37.0' C	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 14:48:16

US3202395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:43
User entered 'Oral (Oral)'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 14:48:16

US3202395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:43
User entered empty.	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 14:48:16

US3202395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:43
User entered '57'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 14:48:16

US3202395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered 'bpm'	System	14 Oct 2020 14:48:16

US3202395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:43
User entered '18'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 14:48:16

US3202395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered 'breaths/min'	System	14 Oct 2020 14:48:16

US3202395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:43
User entered '115'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 14:48:16

US3202395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered 'mmHg'	System	14 Oct 2020 14:48:16

US3202395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:43
User entered '71'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 14:48:16

US3202395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered 'mmHg'	System	14 Oct 2020 14:48:16

US3202395

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	07 Oct 2020 16:07:56

US3202395

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	07 Oct 2020 16:07:56

US3202395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	07 Oct 2020 16:08:19

US3202395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:52

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	07 Oct 2020 16:08:19

US3202395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:52

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 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	07 Oct 2020 16:08:19
	(b) (4)	

US3202395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:52

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered 'MRNA-1273 OR PLACEBO'	System	07 Oct 2020 16:08:19

US3202395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:52

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '7 Oct 2020'	(b) (4) Tiffany Jewell (b) (4)	07 Oct 2020 16:08:19

US3202395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '11:42' reason for change: Data Entry Error	(b) (4)	07 Oct 2020 16:23:36
User entered '12:12'	Tiffany Jewell (b) (4)	07 Oct 2020 16:08:19
	(b) (4)	

US3202395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered '7 Oct 2020 11:42'	System	07 Oct 2020 16:23:36
User entered '7 Oct 2020 12:12'	System	07 Oct 2020 16:08:19

US3202395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Tiffany Jewell (b) (4)	07 Oct 2020 16:08:19

US3202395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered 'ONCE'	System	07 Oct 2020 16:08:19

US3202395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:52

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered 'INTRAMUSCULAR'	System	07 Oct 2020 16:08:19

US3202395

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	07 Oct 2020 16:09:11

US3202395

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:52

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '7 Oct 2020'	(b) (4) Tiffany Jewell (b) (4)	07 Oct 2020 16:09:11

US3202395

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:52

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '11:25'	(b) (4) Tiffany Jewell (b) (4)	07 Oct 2020 16:09:11

US3202395

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:52

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered '7 Oct 2020 11:25'	System	07 Oct 2020 16:09:11

US3202395

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:41:52

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User closed query 'Per GCL Lab Reconciliation: Swab Sample dated 07Oct2020 is recorded under Visit2 Day29 visit in EDC, however a sample is reported under Illness visit dated 29Sep2020 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)	25 Nov 2020 21:15:01
Query 'Per GCL Lab Reconciliation: Swab Sample dated 07Oct2020 is recorded under Visit2 Day29 visit in EDC, however a sample is reported under Illness visit dated 29Sep2020 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 20:37:47
User opened query 'Per GCL Lab Reconciliation: Swab Sample dated 07Oct2020 is recorded under Visit2 Day29 visit in EDC, however a sample is reported under Illness visit dated 29Sep2020 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. '(Site from DM).	(b) (4), (b) (6)	25 Oct 2020 00:12:26
User entered '7 Oct 2020'	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 16:09:22

US3202395

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:41:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 16:09:22

US3202395

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:41:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	07 Oct 2020 16:09:22

US3202395

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:41:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '11:11' reason for change: Data Entry Error	(b) (4)	07 Oct 2020 16:15:24
User entered '11:25'	Tiffany Jewell (b) (4)	07 Oct 2020 16:09:22
	(b) (4)	

US3202395

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered '7 Oct 2020 11:11'	System	07 Oct 2020 16:15:24
User entered '7 Oct 2020 11:25'	System	07 Oct 2020 16:09:22

US3202395

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:41:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 16:09:22

US3202395

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:41:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	07 Oct 2020 16:09:22

US3202395

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:41:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	07 Oct 2020 16:09:22

US3202395

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:41:52

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered empty.	System	07 Oct 2020 16:09:22

US3202395

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	07 Oct 2020 16:08:31

US3202395

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered '1'	System	07 Oct 2020 16:08:31

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	07 Oct 2020 16:08:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-07T12:24:41', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'b736ddd8-e78b-4f31-b5cf-2e3b4ded7358'	System	07 Oct 2020 16:25:08
User entered 'Yes (Y)'	System	07 Oct 2020 16:25:08

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-07T12:24:49', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'b736ddd8-e78b-4f31-b5cf-2e3b4ded7358'	System	07 Oct 2020 16:25:08
User entered '98.6'	System	07 Oct 2020 16:25:08

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-07T12:24:53', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'b736ddd8-e78b-4f31-b5cf-2e3b4ded7358'	System	07 Oct 2020 16:25:08
User entered 'No (N)'	System	07 Oct 2020 16:25:08

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-07T12:25:00', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'b736ddd8-e78b-4f31-b5cf-2e3b4ded7358'	System	07 Oct 2020 16:25:08
User entered '07 Oct 2020 12:25'	System	07 Oct 2020 16:25:08

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '07 Oct 2020 12:02'	System	07 Oct 2020 16:23:36
User entered '07 Oct 2020 12:32'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '07 Oct 2020 14:32'	System	07 Oct 2020 16:23:36
User entered '07 Oct 2020 15:02'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	07 Oct 2020 16:08:19
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-07T20:52:49', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '24d9680c-ba97-4c65-8fbf-ffafef10411d'	System	08 Oct 2020 00:53:13
User entered 'Yes (Y)'	System	08 Oct 2020 00:53:13

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-07T20:53:00', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '24d9680c-ba97-4c65-8fbf-ffafef10411d'	System	08 Oct 2020 00:53:13
User entered '98.8'	System	08 Oct 2020 00:53:13

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-07T20:53:03', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '24d9680c-ba97-4c65-8fbf-ffafef10411d'	System	08 Oct 2020 00:53:13
User entered 'No (N)'	System	08 Oct 2020 00:53:13

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-07T20:53:10', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '24d9680c-ba97-4c65-8fbf-ffafef10411d' User entered '07 Oct 2020 20:53'	System	08 Oct 2020 00:53:13
	System	08 Oct 2020 00:53:13

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '07 Oct 2020 15:27'	System	07 Oct 2020 16:23:36
User entered '07 Oct 2020 15:57'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	07 Oct 2020 16:08:19
User entered 'Day 2'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-08T20:09:40', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '712f0720-a49f-471d-9977-af646112a922'	System	09 Oct 2020 00:09:58
User entered 'Yes (Y)'	System	09 Oct 2020 00:09:58

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-08T20:09:48', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '712f0720-a49f-471d-9977-af646112a922'	System	09 Oct 2020 00:09:58
User entered '98.4'	System	09 Oct 2020 00:09:58

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-08T20:09:51', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '712f0720-a49f-471d-9977-af646112a922'	System	09 Oct 2020 00:09:58
User entered 'No (N)'	System	09 Oct 2020 00:09:58

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-08T20:09:54', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '712f0720-a49f-471d-9977-af646112a922'	System	09 Oct 2020 00:09:58
User entered '08 Oct 2020 20:09'	System	09 Oct 2020 00:09:58

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	07 Oct 2020 16:08:19
User entered 'Day 3'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-09T21:41:19', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '3a2b3d25-8c03-4c77-8681-65ac4d92004c'	System	10 Oct 2020 01:42:28
User entered 'Yes (Y)'	System	10 Oct 2020 01:42:28

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-09T21:42:18', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '3a2b3d25-8c03-4c77-8681-65ac4d92004c' User entered '98.1'	System	10 Oct 2020 01:42:28
	System	10 Oct 2020 01:42:28

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-09T21:42:21', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '3a2b3d25-8c03-4c77-8681-65ac4d92004c'	System	10 Oct 2020 01:42:28
User entered 'No (N)'	System	10 Oct 2020 01:42:28

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-09T21:42:25', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '3a2b3d25-8c03-4c77-8681-65ac4d92004c'	System	10 Oct 2020 01:42:28
User entered '09 Oct 2020 21:42'	System	10 Oct 2020 01:42:28

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	07 Oct 2020 16:08:19
User entered 'Day 4'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-10T21:16:22', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'ac53c806-327b-4b5d-b9d9-1ed4c5beb45a'	System	11 Oct 2020 01:16:39
User entered 'Yes (Y)'	System	11 Oct 2020 01:16:39

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:52

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-10T21:16:29', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'ac53c806-327b-4b5d-b9d9-1ed4c5beb45a'	System	11 Oct 2020 01:16:39
User entered '98.0'	System	11 Oct 2020 01:16:39

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-10T21:16:32', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'ac53c806-327b-4b5d-b9d9-1ed4c5beb45a'	System	11 Oct 2020 01:16:39
User entered 'No (N)'	System	11 Oct 2020 01:16:39

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-10T21:16:36', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'ac53c806-327b-4b5d-b9d9-1ed4c5beb45a'	System	11 Oct 2020 01:16:39
User entered '10 Oct 2020 21:16'	System	11 Oct 2020 01:16:39

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	07 Oct 2020 16:08:19
User entered 'Day 5'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-11T22:18:02', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '254f2b97-4ac3-4521-a117-79042b5e3f41'	System	12 Oct 2020 02:18:21
User entered 'Yes (Y)'	System	12 Oct 2020 02:18:21

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-11T22:18:10', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '254f2b97-4ac3-4521-a117-79042b5e3f41'	System	12 Oct 2020 02:18:21
User entered '98.6'	System	12 Oct 2020 02:18:21

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-11T22:18:13', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '254f2b97-4ac3-4521-a117-79042b5e3f41'	System	12 Oct 2020 02:18:21
User entered 'No (N)'	System	12 Oct 2020 02:18:21

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-11T22:18:17', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '254f2b97-4ac3-4521-a117-79042b5e3f41'	System	12 Oct 2020 02:18:21
User entered '11 Oct 2020 22:18'	System	12 Oct 2020 02:18:21

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	07 Oct 2020 16:08:19
User entered 'Day 6'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-12T22:04:11', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'a97828d7-3e79-48d0-bcf9-c54281c527b6'	System	13 Oct 2020 02:04:37
User entered 'Yes (Y)'	System	13 Oct 2020 02:04:37

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-12T22:04:22', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'a97828d7-3e79-48d0-bcf9-c54281c527b6'	System	13 Oct 2020 02:04:37
User entered '98.5'	System	13 Oct 2020 02:04:37

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-12T22:04:26', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'a97828d7-3e79-48d0-bcf9-c54281c527b6'	System	13 Oct 2020 02:04:37
User entered 'No (N)'	System	13 Oct 2020 02:04:37

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-12T22:04:33', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'a97828d7-3e79-48d0-bcf9-c54281c527b6'	System	13 Oct 2020 02:04:37
User entered '12 Oct 2020 22:04'	System	13 Oct 2020 02:04:37

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	07 Oct 2020 16:08:19
User entered 'Day 7'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bf0fab6f)', Time: '2020-10-13T20:58:26', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '811efb68-a2ea-4d91-b5a8-ee4c87dc0fca'	System	14 Oct 2020 00:59:01
User entered 'Yes (Y)'	System	14 Oct 2020 00:59:01

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-13T20:58:34', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '811efb68-a2ea-4d91-b5a8-ee4c87dc0fca' User entered '96.3'	System	14 Oct 2020 00:59:01
	System	14 Oct 2020 00:59:01

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-13T20:58:42', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '811efb68-a2ea-4d91-b5a8-ee4c87dc0fca'	System	14 Oct 2020 00:59:01
User entered 'Yes (Y)'	System	14 Oct 2020 00:59:01

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
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 'subject contacted. She suffers from chronic back pains and did take Tylenol extra strength to mitigate the pain.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 14:30:52
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)	14 Oct 2020 16:27:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-13T20:58:51', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '811efb68-a2ea-4d91-b5a8-ee4c87dc0fca'	System	14 Oct 2020 00:59:01
User entered '1'	System	14 Oct 2020 00:59:01

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:52

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-13T20:58:51', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '811efb68-a2ea-4d91-b5a8-ee4c87dc0fca'	System	14 Oct 2020 00:59:01
User entered '0'	System	14 Oct 2020 00:59:01

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-13T20:58:59', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '811efb68-a2ea-4d91-b5a8-ee4c87dc0fca' User entered '13 Oct 2020 20:58'	System	14 Oct 2020 00:59:01
	System	14 Oct 2020 00:59:01

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	14 Oct 2020 00:59:01
User entered 'Day 8'	System	14 Oct 2020 00:59:01

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:41:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-14T19:24:21', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '12f6d0ce-1e47-4ddd-9dc2-0d3476ed83f5'	System	14 Oct 2020 23:24:53
User entered 'Yes (Y)'	System	14 Oct 2020 23:24:53

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:41:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-14T19:24:32', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '12f6d0ce-1e47-4ddd-9dc2-0d3476ed83f5'	System	14 Oct 2020 23:24:53
User entered '98.4'	System	14 Oct 2020 23:24:53

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-14T19:24:38', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '12f6d0ce-1e47-4ddd-9dc2-0d3476ed83f5'	System	14 Oct 2020 23:24:53
User entered 'Yes (Y)'	System	14 Oct 2020 23:24:53

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
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 'Subject contacted. She takes Ibuprofen regular for chronic back pain. Not vaccine related ' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 14:30:57
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). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-14T19:24:45', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '12f6d0ce-1e47-4ddd-9dc2-0d3476ed83f5'	Lilian Nukuna (b) (4) (b) (4)	19 Oct 2020 16:09:21
User entered '1'	System	14 Oct 2020 23:24:53
	System	14 Oct 2020 23:24:53
	System	14 Oct 2020 23:24:53

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:41:52

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-14T19:24:45', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '12f6d0ce-1e47-4ddd-9dc2-0d3476ed83f5'	System	14 Oct 2020 23:24:53
User entered '0'	System	14 Oct 2020 23:24:53

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:41:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-14T19:24:49', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '12f6d0ce-1e47-4ddd-9dc2-0d3476ed83f5'	System	14 Oct 2020 23:24:53
User entered '14 Oct 2020 19:24'	System	14 Oct 2020 23:24:53

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '14 Oct 2020 12:00'	System	14 Oct 2020 00:59:01

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '15 Oct 2020 11:59'	System	14 Oct 2020 00:59:01

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	14 Oct 2020 00:59:01
User entered 'Day 9'	System	14 Oct 2020 00:59:01

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:41:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-15T22:24:25', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'df163869-e94b-4a9e-85f2-e21002a7995f'	System	16 Oct 2020 02:24:48
User entered 'Yes (Y)'	System	16 Oct 2020 02:24:48

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:41:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-15T22:24:34', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'df163869-e94b-4a9e-85f2-e21002a7995f'	System	16 Oct 2020 02:24:48
User entered '97.6'	System	16 Oct 2020 02:24:48

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-15T22:24:39', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'df163869-e94b-4a9e-85f2-e21002a7995f'	System	16 Oct 2020 02:24:48
User entered 'No (N)'	System	16 Oct 2020 02:24:48

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:41:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-15T22:24:45', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'df163869-e94b-4a9e-85f2-e21002a7995f'	System	16 Oct 2020 02:24:48
User entered '15 Oct 2020 22:24'	System	16 Oct 2020 02:24:48

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 00:59:01

US3202395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 00:59:01

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	07 Oct 2020 16:08:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-07T12:25:09', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '2476d872-14c9-4b7f-8057-92b97fa58966'	System	07 Oct 2020 16:25:34
User entered 'None (1)'	System	07 Oct 2020 16:25:34

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-07T12:25:18', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '2476d872-14c9-4b7f-8057-92b97fa58966'	System	07 Oct 2020 16:25:34
User entered 'No (N)'	System	07 Oct 2020 16:25:34

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-07T12:25:21', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '2476d872-14c9-4b7f-8057-92b97fa58966'	System	07 Oct 2020 16:25:34
User entered 'No (N)'	System	07 Oct 2020 16:25:34

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-07T12:25:24', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '2476d872-14c9-4b7f-8057-92b97fa58966'	System	07 Oct 2020 16:25:34
User entered 'None (1)'	System	07 Oct 2020 16:25:34

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-07T12:25:28', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '2476d872-14c9-4b7f-8057-92b97fa58966'	System	07 Oct 2020 16:25:34
User entered '07 Oct 2020 12:25'	System	07 Oct 2020 16:25:34

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '07 Oct 2020 12:02'	System	07 Oct 2020 16:23:36
User entered '07 Oct 2020 12:32'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '07 Oct 2020 14:32'	System	07 Oct 2020 16:23:36
User entered '07 Oct 2020 15:02'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	07 Oct 2020 16:08:19
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-07T20:55:21', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '0e1f045c-6a13-4144-b8a5-d21b0d40fb96'	System	08 Oct 2020 00:55:39
User entered 'None (1)'	System	08 Oct 2020 00:55:39

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-07T20:55:24', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '0e1f045c-6a13-4144-b8a5-d21b0d40fb96'	System	08 Oct 2020 00:55:39
User entered 'No (N)'	System	08 Oct 2020 00:55:39

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-07T20:55:27', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '0e1f045c-6a13-4144-b8a5-d21b0d40fb96'	System	08 Oct 2020 00:55:39
User entered 'No (N)'	System	08 Oct 2020 00:55:39

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-07T20:55:30', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '0e1f045c-6a13-4144-b8a5-d21b0d40fb96'	System	08 Oct 2020 00:55:39
User entered 'None (1)'	System	08 Oct 2020 00:55:39

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-07T20:55:34', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '0e1f045c-6a13-4144-b8a5-d21b0d40fb96'	System	08 Oct 2020 00:55:39
User entered '07 Oct 2020 20:55'	System	08 Oct 2020 00:55:39

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '07 Oct 2020 15:27'	System	07 Oct 2020 16:23:36
User entered '07 Oct 2020 15:57'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	07 Oct 2020 16:08:19
User entered 'Day 2'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-08T20:10:05', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'cbf65d05-0a93-4bba-9cbf-917d365df6a3'	System	09 Oct 2020 00:10:22
User entered 'None (1)'	System	09 Oct 2020 00:10:22

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-08T20:10:10', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'cbf65d05-0a93-4bba-9cbf-917d365df6a3'	System	09 Oct 2020 00:10:22
User entered 'No (N)'	System	09 Oct 2020 00:10:22

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-08T20:10:12', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'cbf65d05-0a93-4bba-9cbf-917d365df6a3'	System	09 Oct 2020 00:10:22
User entered 'No (N)'	System	09 Oct 2020 00:10:22

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-08T20:10:15', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'cbf65d05-0a93-4bba-9cbf-917d365df6a3'	System	09 Oct 2020 00:10:22
User entered 'None (1)'	System	09 Oct 2020 00:10:22

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-08T20:10:18', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'cbf65d05-0a93-4bba-9cbf-917d365df6a3'	System	09 Oct 2020 00:10:22
User entered '08 Oct 2020 20:10'	System	09 Oct 2020 00:10:22

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	07 Oct 2020 16:08:19
User entered 'Day 3'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-09T21:42:31', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '8ef93566-e3ca-488f-a336-b98e3680d100'	System	10 Oct 2020 01:42:45
User entered 'None (1)'	System	10 Oct 2020 01:42:45

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-09T21:42:34', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '8ef93566-e3ca-488f-a336-b98e3680d100'	System	10 Oct 2020 01:42:45
User entered 'No (N)'	System	10 Oct 2020 01:42:45

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-09T21:42:36', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '8ef93566-e3ca-488f-a336-b98e3680d100'	System	10 Oct 2020 01:42:45
User entered 'No (N)'	System	10 Oct 2020 01:42:45

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-09T21:42:39', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '8ef93566-e3ca-488f-a336-b98e3680d100'	System	10 Oct 2020 01:42:45
User entered 'None (1)'	System	10 Oct 2020 01:42:45

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-09T21:42:42', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '8ef93566-e3ca-488f-a336-b98e3680d100'	System	10 Oct 2020 01:42:45
User entered '09 Oct 2020 21:42'	System	10 Oct 2020 01:42:45

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	07 Oct 2020 16:08:19
User entered 'Day 4'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-10T21:15:54', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '2cca981f-e6b7-4e4a-bb0a-0532775110b0'	System	11 Oct 2020 01:16:20
User entered 'None (1)'	System	11 Oct 2020 01:16:20

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-10T21:15:57', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '2cca981f-e6b7-4e4a-bb0a-0532775110b0'	System	11 Oct 2020 01:16:20
User entered 'No (N)'	System	11 Oct 2020 01:16:20

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-10T21:16:04', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '2cca981f-e6b7-4e4a-bb0a-0532775110b0'	System	11 Oct 2020 01:16:20
User entered 'No (N)'	System	11 Oct 2020 01:16:20

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-10T21:16:07', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '2cca981f-e6b7-4e4a-bb0a-0532775110b0'	System	11 Oct 2020 01:16:20
User entered 'None (1)'	System	11 Oct 2020 01:16:20

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-10T21:16:15', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '2cca981f-e6b7-4e4a-bb0a-0532775110b0'	System	11 Oct 2020 01:16:20
User entered '10 Oct 2020 21:16'	System	11 Oct 2020 01:16:20

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	07 Oct 2020 16:08:19
User entered 'Day 5'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-11T22:18:21', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '18d9ad4e-69f5-4bd6-a0df-02921f0e9f1b'	System	12 Oct 2020 02:18:37
User entered 'None (1)'	System	12 Oct 2020 02:18:37

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-11T22:18:23', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '18d9ad4e-69f5-4bd6-a0df-02921f0e9f1b'	System	12 Oct 2020 02:18:37
User entered 'No (N)'	System	12 Oct 2020 02:18:37

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-11T22:18:25', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '18d9ad4e-69f5-4bd6-a0df-02921f0e9f1b'	System	12 Oct 2020 02:18:37
User entered 'No (N)'	System	12 Oct 2020 02:18:37

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-11T22:18:28', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '18d9ad4e-69f5-4bd6-a0df-02921f0e9f1b'	System	12 Oct 2020 02:18:37
User entered 'None (1)'	System	12 Oct 2020 02:18:37

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-11T22:18:31', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '18d9ad4e-69f5-4bd6-a0df-02921f0e9f1b'	System	12 Oct 2020 02:18:37
User entered '11 Oct 2020 22:18'	System	12 Oct 2020 02:18:37

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	07 Oct 2020 16:08:19
User entered 'Day 6'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-12T22:04:39', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'e90f810d-7e32-4491-b91b-06be2a9df06d'	System	13 Oct 2020 02:04:55
User entered 'None (1)'	System	13 Oct 2020 02:04:55

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-12T22:04:42', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'e90f810d-7e32-4491-b91b-06be2a9df06d'	System	13 Oct 2020 02:04:55
User entered 'No (N)'	System	13 Oct 2020 02:04:55

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-12T22:04:45', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'e90f810d-7e32-4491-b91b-06be2a9df06d'	System	13 Oct 2020 02:04:55
User entered 'No (N)'	System	13 Oct 2020 02:04:55

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-12T22:04:48', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'e90f810d-7e32-4491-b91b-06be2a9df06d'	System	13 Oct 2020 02:04:55
User entered 'None (1)'	System	13 Oct 2020 02:04:55

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-12T22:04:51', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'e90f810d-7e32-4491-b91b-06be2a9df06d'	System	13 Oct 2020 02:04:55
User entered '12 Oct 2020 22:04'	System	13 Oct 2020 02:04:55

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	07 Oct 2020 16:08:19
User entered 'Day 7'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-13T20:59:05', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '5b5b849e-1a49-4c15-a95a-91fdd36081d4'	System	14 Oct 2020 00:59:20
User entered 'None (1)'	System	14 Oct 2020 00:59:20

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-13T20:59:08', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '5b5b849e-1a49-4c15-a95a-91fdd36081d4'	System	14 Oct 2020 00:59:20
User entered 'No (N)'	System	14 Oct 2020 00:59:20

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-13T20:59:10', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '5b5b849e-1a49-4c15-a95a-91fdd36081d4'	System	14 Oct 2020 00:59:20
User entered 'No (N)'	System	14 Oct 2020 00:59:20

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-13T20:59:13', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '5b5b849e-1a49-4c15-a95a-91fdd36081d4'	System	14 Oct 2020 00:59:20
User entered 'None (1)'	System	14 Oct 2020 00:59:20

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bf0fab6f)', Time: '2020-10-13T20:59:16', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '5b5b849e-1a49-4c15-a95a-91fdd36081d4'	System	14 Oct 2020 00:59:20
User entered '13 Oct 2020 20:59'	System	14 Oct 2020 00:59:20

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	07 Oct 2020 16:08:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-07T12:25:34', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'c452fe8d-6cde-4d89-b79f-f896dff46b96'	System	07 Oct 2020 16:26:08
User entered 'None (0)'	System	07 Oct 2020 16:26:08

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-07T12:25:38', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'c452fe8d-6cde-4d89-b79f-f896dff46b96'	System	07 Oct 2020 16:26:08
User entered 'None (0)'	System	07 Oct 2020 16:26:08

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-07T12:25:43', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'c452fe8d-6cde-4d89-b79f-f896dff46b96'	System	07 Oct 2020 16:26:08
User entered 'None (0)'	System	07 Oct 2020 16:26:08

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-07T12:25:46', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'c452fe8d-6cde-4d89-b79f-f896dff46b96'	System	07 Oct 2020 16:26:08
User entered 'None (0)'	System	07 Oct 2020 16:26:08

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-07T12:25:51', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'c452fe8d-6cde-4d89-b79f-f896dff46b96'	System	07 Oct 2020 16:26:08
User entered 'None (0)'	System	07 Oct 2020 16:26:08

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-07T12:25:53', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'c452fe8d-6cde-4d89-b79f-f896dff46b96'	System	07 Oct 2020 16:26:08
User entered 'None (0)'	System	07 Oct 2020 16:26:08

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-07T12:25:58', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'c452fe8d-6cde-4d89-b79f-f896dff46b96'	System	07 Oct 2020 16:26:08
User entered 'No (N)'	System	07 Oct 2020 16:26:08

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-07T12:26:04', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'c452fe8d-6cde-4d89-b79f-f896dff46b96'	System	07 Oct 2020 16:26:08
User entered '07 Oct 2020 12:26'	System	07 Oct 2020 16:26:08

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '07 Oct 2020 12:02'	System	07 Oct 2020 16:23:36
User entered '07 Oct 2020 12:32'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '07 Oct 2020 14:32'	System	07 Oct 2020 16:23:36
User entered '07 Oct 2020 15:02'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	07 Oct 2020 16:08:19
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-07T20:55:39', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'd6c61b3e-ff3b-4622-999a-eef48e0d48af'	System	08 Oct 2020 00:56:07
User entered 'None (0)'	System	08 Oct 2020 00:56:07

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-07T20:55:42', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'd6c61b3e-ff3b-4622-999a-eef48e0d48af'	System	08 Oct 2020 00:56:07
User entered 'None (0)'	System	08 Oct 2020 00:56:07

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-07T20:55:45', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'd6c61b3e-ff3b-4622-999a-eef48e0d48af'	System	08 Oct 2020 00:56:07
User entered 'None (0)'	System	08 Oct 2020 00:56:07

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-07T20:55:49', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'd6c61b3e-ff3b-4622-999a-eef48e0d48af' User entered 'None (0)'	System	08 Oct 2020 00:56:07
	System	08 Oct 2020 00:56:07

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-07T20:55:51', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'd6c61b3e-ff3b-4622-999a-eef48e0d48af'	System	08 Oct 2020 00:56:07
User entered 'None (0)'	System	08 Oct 2020 00:56:07

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-07T20:55:53', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'd6c61b3e-ff3b-4622-999a-eef48e0d48af'	System	08 Oct 2020 00:56:07
User entered 'None (0)'	System	08 Oct 2020 00:56:07

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-07T20:55:57', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'd6c61b3e-ff3b-4622-999a-eef48e0d48af'	System	08 Oct 2020 00:56:07
User entered 'No (N)'	System	08 Oct 2020 00:56:07

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-07T20:56:02', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'd6c61b3e-ff3b-4622-999a-eef48e0d48af' User entered '07 Oct 2020 20:56'	System	08 Oct 2020 00:56:07
	System	08 Oct 2020 00:56:07

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '07 Oct 2020 15:27'	System	07 Oct 2020 16:23:36
User entered '07 Oct 2020 15:57'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	07 Oct 2020 16:08:19
User entered 'Day 2'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bf0fab6f)', Time: '2020-10-08T20:10:23', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '96aeebf4-e71b-4d6b-98d2-b14d4da1c0e6'	System	09 Oct 2020 00:10:44
User entered 'None (0)'	System	09 Oct 2020 00:10:44

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-08T20:10:26', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '96aeebf4-e71b-4d6b-98d2-b14d4da1c0e6'	System	09 Oct 2020 00:10:44
User entered 'None (0)'	System	09 Oct 2020 00:10:44

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-08T20:10:28', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '96aeebf4-e71b-4d6b-98d2-b14d4da1c0e6'	System	09 Oct 2020 00:10:44
User entered 'None (0)'	System	09 Oct 2020 00:10:44

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-08T20:10:30', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '96aeebf4-e71b-4d6b-98d2-b14d4da1c0e6'	System	09 Oct 2020 00:10:44
User entered 'None (0)'	System	09 Oct 2020 00:10:44

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-08T20:10:32', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '96aeebf4-e71b-4d6b-98d2-b14d4da1c0e6'	System	09 Oct 2020 00:10:44
User entered 'None (0)'	System	09 Oct 2020 00:10:44

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-08T20:10:34', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '96aeebf4-e71b-4d6b-98d2-b14d4da1c0e6'	System	09 Oct 2020 00:10:44
User entered 'None (0)'	System	09 Oct 2020 00:10:44

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-08T20:10:38', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '96aeebf4-e71b-4d6b-98d2-b14d4da1c0e6'	System	09 Oct 2020 00:10:44
User entered 'No (N)'	System	09 Oct 2020 00:10:44

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-08T20:10:41', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '96aeebf4-e71b-4d6b-98d2-b14d4da1c0e6'	System	09 Oct 2020 00:10:44
User entered '08 Oct 2020 20:10'	System	09 Oct 2020 00:10:44

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	07 Oct 2020 16:08:19
User entered 'Day 3'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-09T21:42:50', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '50cc2954-6041-4c2c-9042-3aecc3043392'	System	10 Oct 2020 01:43:13
User entered 'None (0)'	System	10 Oct 2020 01:43:13

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-09T21:42:54', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '50cc2954-6041-4c2c-9042-3aecc3043392'	System	10 Oct 2020 01:43:13
User entered 'None (0)'	System	10 Oct 2020 01:43:13

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-09T21:42:57', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '50cc2954-6041-4c2c-9042-3aecc3043392'	System	10 Oct 2020 01:43:13
User entered 'None (0)'	System	10 Oct 2020 01:43:13

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-09T21:42:59', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '50cc2954-6041-4c2c-9042-3aecc3043392'	System	10 Oct 2020 01:43:13
User entered 'None (0)'	System	10 Oct 2020 01:43:13

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-09T21:43:01', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '50cc2954-6041-4c2c-9042-3aecc3043392'	System	10 Oct 2020 01:43:13
User entered 'None (0)'	System	10 Oct 2020 01:43:13

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-09T21:43:03', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '50cc2954-6041-4c2c-9042-3aecc3043392'	System	10 Oct 2020 01:43:13
User entered 'None (0)'	System	10 Oct 2020 01:43:13

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-09T21:43:07', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '50cc2954-6041-4c2c-9042-3aecc3043392'	System	10 Oct 2020 01:43:13
User entered 'No (N)'	System	10 Oct 2020 01:43:13

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-09T21:43:10', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '50cc2954-6041-4c2c-9042-3aecc3043392'	System	10 Oct 2020 01:43:13
User entered '09 Oct 2020 21:43'	System	10 Oct 2020 01:43:13

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	07 Oct 2020 16:08:19
User entered 'Day 4'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-10T21:16:41', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '4810c134-e8b9-4d4b-b6a7-e8d45bc1c746'	System	11 Oct 2020 01:17:01
User entered 'None (0)'	System	11 Oct 2020 01:17:01

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-10T21:16:43', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '4810c134-e8b9-4d4b-b6a7-e8d45bc1c746'	System	11 Oct 2020 01:17:01
User entered 'None (0)'	System	11 Oct 2020 01:17:01

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-10T21:16:45', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '4810c134-e8b9-4d4b-b6a7-e8d45bc1c746'	System	11 Oct 2020 01:17:01
User entered 'None (0)'	System	11 Oct 2020 01:17:01

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-10T21:16:47', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '4810c134-e8b9-4d4b-b6a7-e8d45bc1c746'	System	11 Oct 2020 01:17:01
User entered 'None (0)'	System	11 Oct 2020 01:17:01

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-10T21:16:49', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '4810c134-e8b9-4d4b-b6a7-e8d45bc1c746'	System	11 Oct 2020 01:17:01
User entered 'None (0)'	System	11 Oct 2020 01:17:01

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bf0fab6f)', Time: '2020-10-10T21:16:51', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '4810c134-e8b9-4d4b-b6a7-e8d45bc1c746'	System	11 Oct 2020 01:17:01
User entered 'None (0)'	System	11 Oct 2020 01:17:01

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-10T21:16:54', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '4810c134-e8b9-4d4b-b6a7-e8d45bc1c746'	System	11 Oct 2020 01:17:01
User entered 'No (N)'	System	11 Oct 2020 01:17:01

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-10T21:16:58', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '4810c134-e8b9-4d4b-b6a7-e8d45bc1c746'	System	11 Oct 2020 01:17:01
User entered '10 Oct 2020 21:16'	System	11 Oct 2020 01:17:01

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	07 Oct 2020 16:08:19
User entered 'Day 5'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-11T22:18:37', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'b1591e58-aa0a-47d0-a97f-dfba72b22fd8'	System	12 Oct 2020 02:19:11
User entered 'None (0)'	System	12 Oct 2020 02:19:11

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-11T22:18:40', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'b1591e58-aa0a-47d0-a97f-dfba72b22fd8'	System	12 Oct 2020 02:19:11
User entered 'None (0)'	System	12 Oct 2020 02:19:11

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-11T22:18:43', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'b1591e58-aa0a-47d0-a97f-dfba72b22fd8'	System	12 Oct 2020 02:19:11
User entered 'None (0)'	System	12 Oct 2020 02:19:11

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-11T22:18:45', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'b1591e58-aa0a-47d0-a97f-dfba72b22fd8'	System	12 Oct 2020 02:19:11
User entered 'None (0)'	System	12 Oct 2020 02:19:11

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-11T22:18:49', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'b1591e58-aa0a-47d0-a97f-dfba72b22fd8'	System	12 Oct 2020 02:19:11
User entered 'None (0)'	System	12 Oct 2020 02:19:11

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-11T22:18:51', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'b1591e58-aa0a-47d0-a97f-dfba72b22fd8'	System	12 Oct 2020 02:19:11
User entered 'None (0)'	System	12 Oct 2020 02:19:11

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-11T22:18:54', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'b1591e58-aa0a-47d0-a97f-dfba72b22fd8'	System	12 Oct 2020 02:19:11
User entered 'No (N)'	System	12 Oct 2020 02:19:11

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-11T22:18:57', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'b1591e58-aa0a-47d0-a97f-dfba72b22fd8'	System	12 Oct 2020 02:19:11
User entered '11 Oct 2020 22:18'	System	12 Oct 2020 02:19:11

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	07 Oct 2020 16:08:19
User entered 'Day 6'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-12T22:04:58', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '0b416e43-02e3-47ce-905c-1bb2ee2a3bee'	System	13 Oct 2020 02:05:54
User entered 'None (0)'	System	13 Oct 2020 02:05:54

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-12T22:05:14', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '0b416e43-02e3-47ce-905c-1bb2ee2a3bee'	System	13 Oct 2020 02:05:54
User entered 'Some interference with activity (2)'	System	13 Oct 2020 02:05:54

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-12T22:05:24', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '0b416e43-02e3-47ce-905c-1bb2ee2a3bee'	System	13 Oct 2020 02:05:54
User entered 'None (0)'	System	13 Oct 2020 02:05:54

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bf0fab6f)', Time: '2020-10-12T22:05:35', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '0b416e43-02e3-47ce-905c-1bb2ee2a3bee'	System	13 Oct 2020 02:05:54
User entered 'None (0)'	System	13 Oct 2020 02:05:54

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-12T22:05:39', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '0b416e43-02e3-47ce-905c-1bb2ee2a3bee'	System	13 Oct 2020 02:05:54
User entered 'None (0)'	System	13 Oct 2020 02:05:54

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-12T22:05:42', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '0b416e43-02e3-47ce-905c-1bb2ee2a3bee'	System	13 Oct 2020 02:05:54
User entered 'None (0)'	System	13 Oct 2020 02:05:54

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-12T22:05:45', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '0b416e43-02e3-47ce-905c-1bb2ee2a3bee'	System	13 Oct 2020 02:05:54
User entered 'No (N)'	System	13 Oct 2020 02:05:54

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-12T22:05:52', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '0b416e43-02e3-47ce-905c-1bb2ee2a3bee'	System	13 Oct 2020 02:05:54
User entered '12 Oct 2020 22:05'	System	13 Oct 2020 02:05:54

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	07 Oct 2020 16:08:19
User entered 'Day 7'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-13T20:59:38', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '2d1685f2-79c2-47fa-bca5-73dd044025ea'	System	14 Oct 2020 01:00:37
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	14 Oct 2020 01:00:37

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-13T20:59:43', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '2d1685f2-79c2-47fa-bca5-73dd044025ea'	System	14 Oct 2020 01:00:37
User entered 'Some interference with activity (2)'	System	14 Oct 2020 01:00:37

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-13T20:59:47', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '2d1685f2-79c2-47fa-bca5-73dd044025ea'	System	14 Oct 2020 01:00:37
User entered 'None (0)'	System	14 Oct 2020 01:00:37

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-13T21:00:09', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '2d1685f2-79c2-47fa-bca5-73dd044025ea'	System	14 Oct 2020 01:00:37
User entered 'None (0)'	System	14 Oct 2020 01:00:37

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-13T21:00:13', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '2d1685f2-79c2-47fa-bca5-73dd044025ea'	System	14 Oct 2020 01:00:37
User entered 'None (0)'	System	14 Oct 2020 01:00:37

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-13T21:00:16', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '2d1685f2-79c2-47fa-bca5-73dd044025ea'	System	14 Oct 2020 01:00:37
User entered 'None (0)'	System	14 Oct 2020 01:00:37

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-13T21:00:19', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '2d1685f2-79c2-47fa-bca5-73dd044025ea'	System	14 Oct 2020 01:00:37
User entered 'No (N)'	System	14 Oct 2020 01:00:37

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-13T21:00:31', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '2d1685f2-79c2-47fa-bca5-73dd044025ea'	System	14 Oct 2020 01:00:37
User entered '13 Oct 2020 21:00'	System	14 Oct 2020 01:00:37

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 16:08:19

US3202395

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	14 Oct 2020 01:00:37
User entered 'Day 8'	System	14 Oct 2020 01:00:37

US3202395

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-14T19:25:31', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'cf4de6a0-7e2d-4547-bbe8-ce2dbf145395'	System	14 Oct 2020 23:25:38
User entered 'No interference with activity (1)'	System	14 Oct 2020 23:25:38

US3202395

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:41:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-14T19:25:37', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'cf4de6a0-7e2d-4547-bbe8-ce2dbf145395'	System	14 Oct 2020 23:25:38
User entered '14 Oct 2020 19:25'	System	14 Oct 2020 23:25:38

US3202395

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '14 Oct 2020 12:00'	System	14 Oct 2020 01:00:37

US3202395

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '15 Oct 2020 11:59'	System	14 Oct 2020 01:00:37

US3202395

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	14 Oct 2020 01:00:37
User entered 'Day 9'	System	14 Oct 2020 01:00:37

US3202395

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-15T22:23:27', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '89a37e36-2168-47e0-acb5-fa03dbe384f7'	System	16 Oct 2020 02:23:36
User entered 'None (0)'	System	16 Oct 2020 02:23:36

US3202395

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:41:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-15T22:23:34', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '89a37e36-2168-47e0-acb5-fa03dbe384f7'	System	16 Oct 2020 02:23:36
User entered '15 Oct 2020 22:23'	System	16 Oct 2020 02:23:36

US3202395

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 01:00:37

US3202395

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 01:00:37

US3202395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	13 Oct 2020 02:05:54
User entered 'Day 8'	System	13 Oct 2020 02:05:54

US3202395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-14T19:25:48', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'ff51a6c1-146f-4fd2-b079-e1e82b4d6f28'	System	14 Oct 2020 23:25:58
User entered 'Some interference with activity (2)'	System	14 Oct 2020 23:25:58

US3202395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:41:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-14T19:25:53', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'ff51a6c1-146f-4fd2-b079-e1e82b4d6f28'	System	14 Oct 2020 23:25:58
User entered '14 Oct 2020 19:25'	System	14 Oct 2020 23:25:58

US3202395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 02:05:54

US3202395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 02:05:54

US3202395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	14 Oct 2020 01:00:37
User entered 'Day 9'	System	14 Oct 2020 01:00:37

US3202395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-15T22:23:51', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '994ffd8a-e30c-4b06-9a71-9d6d99b71ad1'	System	16 Oct 2020 02:23:58
User entered 'No interference with activity (1)'	System	16 Oct 2020 02:23:58

US3202395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:41:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-15T22:23:55', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '994ffd8a-e30c-4b06-9a71-9d6d99b71ad1'	System	16 Oct 2020 02:23:58
User entered '15 Oct 2020 22:23'	System	16 Oct 2020 02:23:58

US3202395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 01:00:37

US3202395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 01:00:37

US3202395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	14 Oct 2020 23:25:58
User entered 'Day 10'	System	14 Oct 2020 23:25:58

US3202395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-16T21:39:01', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'f9adc71b-5fdd-4c56-babb-2240fabcd966'	System	17 Oct 2020 01:39:09
User entered 'No interference with activity (1)'	System	17 Oct 2020 01:39:09

US3202395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:41:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-16T21:39:04', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'f9adc71b-5fdd-4c56-babb-2240fabcd966'	System	17 Oct 2020 01:39:09
User entered '16 Oct 2020 21:39'	System	17 Oct 2020 01:39:09

US3202395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 23:25:58

US3202395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 23:25:58

US3202395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	16 Oct 2020 02:23:58
User entered 'Day 11'	System	16 Oct 2020 02:23:58

US3202395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36

US3202395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 15:41:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36

US3202395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 02:23:58

US3202395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 02:23:58

US3202395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	17 Oct 2020 01:39:09
User entered 'Day 12'	System	17 Oct 2020 01:39:09

US3202395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36

US3202395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 15:41:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36

US3202395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '18 Oct 2020 12:00'	System	17 Oct 2020 01:39:09

US3202395

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '19 Oct 2020 11:59'	System	17 Oct 2020 01:39:09

US3202395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	13 Oct 2020 02:05:54
User entered 'Day 8'	System	13 Oct 2020 02:05:54

US3202395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-14T19:25:58', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'e32ea183-22f5-47e1-b996-b3fcc82f1f06'	System	14 Oct 2020 23:26:08
User entered 'No (N)'	System	14 Oct 2020 23:26:08

US3202395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:41:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-14T19:26:02', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'e32ea183-22f5-47e1-b996-b3fcc82f1f06'	System	14 Oct 2020 23:26:08
User entered '14 Oct 2020 19:26'	System	14 Oct 2020 23:26:08

US3202395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 02:05:54

US3202395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 02:05:54

US3202395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	14 Oct 2020 00:59:01
User entered 'Day 9'	System	14 Oct 2020 00:59:01

US3202395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-15T22:24:02', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '6f48ed40-09fe-4ff1-8bda-89fe2cea2997'	System	16 Oct 2020 02:24:09
User entered 'No (N)'	System	16 Oct 2020 02:24:09

US3202395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:41:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-15T22:24:06', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '6f48ed40-09fe-4ff1-8bda-89fe2cea2997'	System	16 Oct 2020 02:24:09
User entered '15 Oct 2020 22:24'	System	16 Oct 2020 02:24:09

US3202395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 00:59:01

US3202395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 00:59:01

US3202395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	14 Oct 2020 23:24:53
User entered 'Day 10'	System	14 Oct 2020 23:24:53

US3202395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-16T21:39:13', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '245d3a52-592d-4810-bcbd-ff4f30b87d83'	System	17 Oct 2020 01:39:19
User entered 'No (N)'	System	17 Oct 2020 01:39:19

US3202395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:41:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-10-16T21:39:16', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '245d3a52-592d-4810-bcbd-ff4f30b87d83'	System	17 Oct 2020 01:39:19
User entered '16 Oct 2020 21:39'	System	17 Oct 2020 01:39:19

US3202395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 23:24:53

US3202395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 23:24:53

US3202395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	16 Oct 2020 02:23:58
User entered 'Day 11'	System	16 Oct 2020 02:23:58

US3202395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36

US3202395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:41:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36

US3202395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 02:23:58

US3202395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 02:23:58

US3202395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	17 Oct 2020 01:39:09
User entered 'Day 12'	System	17 Oct 2020 01:39:09

US3202395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 15:41:52

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 04:54:36

US3202395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 15:41:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36

US3202395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 15:41:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '18 Oct 2020 12:00'	System	17 Oct 2020 01:39:09

US3202395

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 15:41:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
User entered '19 Oct 2020 11:59'	System	17 Oct 2020 01:39:09

US3202395

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 14:53:07

US3202395

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) System	14 Oct 2020 14:57:03
Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	14 Oct 2020 14:57:03
User entered '14 Oct 2020' reason for change: Data Entry Error	Teresa Deese (b) (4)	14 Oct 2020 14:57:03
User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	14 Oct 2020 14:53:07
User entered '10 Sep 2020'	Teresa Deese (b) (4)	14 Oct 2020 14:53:07

US3202395

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 14:53:07

US3202395

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered empty.	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 14:53:07

US3202395

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 14:57:16

US3202395

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered '1'	System	14 Oct 2020 14:57:16

US3202395

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	24 Oct 2020 13:05:46
	(b) (4)	

US3202395

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '24 Oct 2020'	(b) (4) zackery harmon (b) (4)	24 Oct 2020 13:05:46
	(b) (4)	

US3202395

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) zackery harmon (b) (4)	24 Oct 2020 13:05:46

US3202395

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'LVM attempts x3'	(b) (4) zackery harmon (b) (4)	24 Oct 2020 13:05:46
	(b) (4)	

US3202395

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	24 Oct 2020 13:05:50
	(b) (4)	

US3202395

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered '1'	System	24 Oct 2020 13:05:50

US3202395

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	04 Nov 2020 20:12:03

US3202395

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered '28 Oct 2020'	(b) (4) Lilian Nukuna (b) (4)	04 Nov 2020 20:12:03

US3202395

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4)	04 Nov 2020 20:12:03

US3202395

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered empty.	(b) (4) Lilian Nukuna (b) (4)	04 Nov 2020 20:12:03
	(b) (4)	

US3202395

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:55:01

US3202395

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered '1'	System	04 Nov 2020 18:55:01

US3202395

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:57:19

US3202395

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:52

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:43
User entered '04 Nov 2020'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:57:19

US3202395

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:52

[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 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:43
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:57:19

US3202395

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered 'VISIT3'	System	04 Nov 2020 18:57:19

US3202395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:59:32

US3202395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:43
User entered '04 Nov 2020'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:59:32

US3202395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:43
User entered '10:44'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:59:32

US3202395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered '04 Nov 2020 10:44'	System	04 Nov 2020 18:59:32

US3202395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:43
User entered '37.0' C	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:59:32

US3202395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:43
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:59:32

US3202395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:43
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:59:32

US3202395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:43
User entered '84'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:59:32

US3202395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered 'bpm'	System	04 Nov 2020 18:59:32

US3202395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:43
User entered '16'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:59:32

US3202395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered 'breaths/min'	System	04 Nov 2020 18:59:32

US3202395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:43
User entered '121'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:59:32

US3202395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered 'mmHg'	System	04 Nov 2020 18:59:32

US3202395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:43
User entered '79'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:59:32

US3202395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered 'mmHg'	System	04 Nov 2020 18:59:32

US3202395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13

US3202395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13

US3202395

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:59:46

US3202395

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:43
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:59:46

US3202395

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:00:26

US3202395

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:52

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:43
User entered '04 Nov 2020'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:00:26

US3202395

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:52

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:43
User entered '10:53'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:00:26

US3202395

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered '04 Nov 2020 10:53'	System	04 Nov 2020 19:00:26

US3202395

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:31:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:00:35

US3202395

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered '1'	System	04 Nov 2020 19:00:35

US3202395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	03 Sep 2020 17:46:50
User entered 'Day 64'	System	03 Sep 2020 17:46:50

US3202395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-11-04T21:39:51', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'ea2d3c6f-1eb7-4701-83ef-552a59d92a0c'	System	05 Nov 2020 02:40:03
User entered 'No (N)'	System	05 Nov 2020 02:40:03

US3202395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

Have you been exposed to someone with 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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-11-04T21:39:55', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'ea2d3c6f-1eb7-4701-83ef-552a59d92a0c'	System	05 Nov 2020 02:40:03
User entered 'No (N)'	System	05 Nov 2020 02:40:03

US3202395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-11-04T21:40:00', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'ea2d3c6f-1eb7-4701-83ef-552a59d92a0c'	System	05 Nov 2020 02:40:03
User entered '04 Nov 2020 21:40:00'	System	05 Nov 2020 02:40:03

US3202395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	03 Sep 2020 17:46:50
User entered '03 Nov 2020 00:01'	System	03 Sep 2020 17:46:50

US3202395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	03 Sep 2020 17:46:50
User entered '07 Nov 2020 23:59'	System	03 Sep 2020 17:46:50

US3202395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	03 Sep 2020 17:46:50
User entered 'Day 71'	System	03 Sep 2020 17:46:50

US3202395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-11-10T17:54:40', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '38d438ca-593f-4fbb-87dd-c789e054eafc'	System	10 Nov 2020 22:54:54
User entered 'No (N)'	System	10 Nov 2020 22:54:54

US3202395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

Have you been exposed to someone with 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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-11-10T17:54:45', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '38d438ca-593f-4fbb-87dd-c789e054eafc'	System	10 Nov 2020 22:54:54
User entered 'No (N)'	System	10 Nov 2020 22:54:54

US3202395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-11-10T17:54:50', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '38d438ca-593f-4fbb-87dd-c789e054eafc' User entered '10 Nov 2020 17:54:50'	System	10 Nov 2020 22:54:54
	System	10 Nov 2020 22:54:54

US3202395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	03 Sep 2020 17:46:50
User entered '10 Nov 2020 00:01'	System	03 Sep 2020 17:46:50

US3202395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	03 Sep 2020 17:46:50
User entered '14 Nov 2020 23:59'	System	03 Sep 2020 17:46:50

US3202395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	03 Sep 2020 17:46:50
User entered 'Day 78'	System	03 Sep 2020 17:46:50

US3202395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-11-17T09:16:41', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'e7d729ad-19dc-4af3-9020-0cad7ec9b42c'	System	17 Nov 2020 14:16:58
User entered 'No (N)'	System	17 Nov 2020 14:16:58

US3202395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

Have you been exposed to someone with 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 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-11-17T09:16:47', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'e7d729ad-19dc-4af3-9020-0cad7ec9b42c'	System	17 Nov 2020 14:16:58
User entered 'No (N)'	System	17 Nov 2020 14:16:58

US3202395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2020-11-17T09:16:55', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'e7d729ad-19dc-4af3-9020-0cad7ec9b42c'	System	17 Nov 2020 14:16:58
User entered '17 Nov 2020 09:16:55'	System	17 Nov 2020 14:16:58

US3202395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	03 Sep 2020 17:46:50
User entered '17 Nov 2020 00:01'	System	03 Sep 2020 17:46:50

US3202395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:54:36
Data entry locked.	System	03 Sep 2020 17:46:50
User entered '21 Nov 2020 23:59'	System	03 Sep 2020 17:46:50

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[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 (c00cae2bfb0fab6f)', Time: '2020-11-24T08:44:08', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'a4f317bb-85cf-4336-8138-8d445fd2cfc9'	System	24 Nov 2020 13:44:19
User entered 'No (N)'	System	24 Nov 2020 13:44:19

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

Have you been exposed to someone with 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 (c00cae2bfb0fab6f)', Time: '2020-11-24T08:44:12', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'a4f317bb-85cf-4336-8138-8d445fd2cfc9'	System	24 Nov 2020 13:44:19
User entered 'No (N)'	System	24 Nov 2020 13:44:19

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bf0fab6f)', Time: '2020-11-24T08:44:16', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'a4f317bb-85cf-4336-8138-8d445fd2cfc9'	System	24 Nov 2020 13:44:19
User entered '24 Nov 2020 08:44:16'	System	24 Nov 2020 13:44:19

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[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 (c00cae2bfb0fab6f)', Time: '2020-12-14T09:00:19', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '3a082388-ed88-4fb3-ac49-f4b5c95cc735'	System	14 Dec 2020 14:01:02
User entered 'No (N)'	System	14 Dec 2020 14:01:02

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

Have you been exposed to someone with 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 (c00cae2bfb0fab6f)', Time: '2020-12-14T09:00:49', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '3a082388-ed88-4fb3-ac49-f4b5c95cc735'	System	14 Dec 2020 14:01:02
User entered 'No (N)'	System	14 Dec 2020 14:01:02

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bf0fab6f)', Time: '2020-12-14T09:00:57', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '3a082388-ed88-4fb3-ac49-f4b5c95cc735'	System	14 Dec 2020 14:01:02
User entered '14 Dec 2020 09:00:57'	System	14 Dec 2020 14:01:02

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[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 (c00cae2bfb0fab6f)', Time: '2020-12-22T19:17:43', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'b78f03ec-5f07-4ed8-ba99-ea6c5a0bd29a'	System	23 Dec 2020 00:17:57
User entered 'No (N)'	System	23 Dec 2020 00:17:57

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

Have you been exposed to someone with 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 (c00cae2bfb0fab6f)', Time: '2020-12-22T19:17:47', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'b78f03ec-5f07-4ed8-ba99-ea6c5a0bd29a'	System	23 Dec 2020 00:17:57
User entered 'No (N)'	System	23 Dec 2020 00:17:57

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bf0fab6f)', Time: '2020-12-22T19:17:51', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'b78f03ec-5f07-4ed8-ba99-ea6c5a0bd29a'	System	23 Dec 2020 00:17:57
User entered '22 Dec 2020 19:17:51'	System	23 Dec 2020 00:17:57

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[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 (c00cae2bfb0fab6f)', Time: '2021-01-02T16:33:37', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'ead50708-71f6-432e-aea5-c083d97ba6cf'	System	02 Jan 2021 21:34:18
User entered 'No (N)'	System	02 Jan 2021 21:34:18

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

Have you been exposed to someone with 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 (c00cae2bfb0fab6f)', Time: '2021-01-02T16:34:10', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'ead50708-71f6-432e-aea5-c083d97ba6cf'	System	02 Jan 2021 21:34:18
User entered 'No (N)'	System	02 Jan 2021 21:34:18

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bf0fab6f)', Time: '2021-01-02T16:34:15', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'ead50708-71f6-432e-aea5-c083d97ba6cf' User entered '02 Jan 2021 16:34:15'	System	02 Jan 2021 21:34:18
	System	02 Jan 2021 21:34:18

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[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 (c00cae2bfb0fab6f)', Time: '2021-01-20T13:44:28', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'a4335f62-f954-441a-9cfe-340f8f14be6d'	System	20 Jan 2021 18:44:38
User entered 'No (N)'	System	20 Jan 2021 18:44:38

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

Have you been exposed to someone with 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 (c00cae2bfb0fab6f)', Time: '2021-01-20T13:44:31', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'a4335f62-f954-441a-9cfe-340f8f14be6d' User entered 'No (N)'	System	20 Jan 2021 18:44:38
	System	20 Jan 2021 18:44:38

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bf0fab6f)', Time: '2021-01-20T13:44:37', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'a4335f62-f954-441a-9cfe-340f8f14be6d' User entered '20 Jan 2021 13:44:37'	System	20 Jan 2021 18:44:38
	System	20 Jan 2021 18:44:38

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[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 (c00cae2bfb0fab6f)', Time: '2021-02-01T20:24:25', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '6ec52c21-77ee-45d9-a3cd-a01263ca45c3'	System	02 Feb 2021 01:24:42
User entered 'No (N)'	System	02 Feb 2021 01:24:42

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

Have you been exposed to someone with 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 (c00cae2bfb0fab6f)', Time: '2021-02-01T20:24:31', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '6ec52c21-77ee-45d9-a3cd-a01263ca45c3'	System	02 Feb 2021 01:24:42
User entered 'No (N)'	System	02 Feb 2021 01:24:42

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2021-02-01T20:24:38', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '6ec52c21-77ee-45d9-a3cd-a01263ca45c3'	System	02 Feb 2021 01:24:42
User entered '01 Feb 2021 20:24:38'	System	02 Feb 2021 01:24:42

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[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 (c00cae2bfb0fab6f)', Time: '2021-02-06T22:30:07', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '5493f9d6-7a32-43db-bdea-dcad228c415f' User entered 'No (N)'	System	07 Feb 2021 03:30:17
	System	07 Feb 2021 03:30:17

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

Have you been exposed to someone with 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 (c00cae2bfb0fab6f)', Time: '2021-02-06T22:30:11', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '5493f9d6-7a32-43db-bdea-dcad228c415f'	System	07 Feb 2021 03:30:17
User entered 'No (N)'	System	07 Feb 2021 03:30:17

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bf0fab6f)', Time: '2021-02-06T22:30:15', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '5493f9d6-7a32-43db-bdea-dcad228c415f'	System	07 Feb 2021 03:30:17
User entered '06 Feb 2021 22:30:15'	System	07 Feb 2021 03:30:17

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[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 (c00cae2bfb0fab6f)', Time: '2021-02-13T22:40:58', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '1a26a147-1e33-4d6f-b7e3-7930316906b6'	System	14 Feb 2021 03:41:11
User entered 'No (N)'	System	14 Feb 2021 03:41:11

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

Have you been exposed to someone with 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 (c00cae2bfb0fab6f)', Time: '2021-02-13T22:41:02', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '1a26a147-1e33-4d6f-b7e3-7930316906b6'	System	14 Feb 2021 03:41:11
User entered 'No (N)'	System	14 Feb 2021 03:41:11

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2021-02-13T22:41:07', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '1a26a147-1e33-4d6f-b7e3-7930316906b6'	System	14 Feb 2021 03:41:11
User entered '13 Feb 2021 22:41:07'	System	14 Feb 2021 03:41:11

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[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 (c00cae2bfb0fab6f)', Time: '2021-02-20T08:54:25', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '86bfe2b9-0e5f-4915-b23b-0c136e154c5f'	System	20 Feb 2021 13:54:55
User entered 'No (N)'	System	20 Feb 2021 13:54:55

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

Have you been exposed to someone with 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 (c00cae2bfb0fab6f)', Time: '2021-02-20T08:54:30', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '86bfe2b9-0e5f-4915-b23b-0c136e154c5f'	System	20 Feb 2021 13:54:55
User entered 'No (N)'	System	20 Feb 2021 13:54:55

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bf0fab6f)', Time: '2021-02-20T08:54:52', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '86bfe2b9-0e5f-4915-b23b-0c136e154c5f' User entered '20 Feb 2021 08:54:52'	System	20 Feb 2021 13:54:55
	System	20 Feb 2021 13:54:55

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[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 (c00cae2bfb0fab6f)', Time: '2021-03-01T07:45:47-05:00', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '466ba4b0-4852-4876-a9e5-339c953a7d82'	System	01 Mar 2021 12:45:58
User entered 'No (N)'	System	01 Mar 2021 12:45:58

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

Have you been exposed to someone with 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 (c00cae2bfb0fab6f)', Time: '2021-03-01T07:45:52-05:00', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '466ba4b0-4852-4876-a9e5-339c953a7d82'	System	01 Mar 2021 12:45:58
User entered 'No (N)'	System	01 Mar 2021 12:45:58

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2021-03-01T07:45:58-05:00', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '466ba4b0-4852-4876-a9e5-339c953a7d82'	System	01 Mar 2021 12:45:58
User entered '01 Mar 2021 07:45:58'	System	01 Mar 2021 12:45:58

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[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 (c00cae2bfb0fab6f)', Time: '2021-03-06T08:08:49-05:00', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '45c7f023-9074-48fa-a572-b612a1329ca6'	System	06 Mar 2021 13:09:00
User entered 'No (N)'	System	06 Mar 2021 13:09:00

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

Have you been exposed to someone with 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 (c00cae2bfb0fab6f)', Time: '2021-03-06T08:08:53-05:00', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '45c7f023-9074-48fa-a572-b612a1329ca6'	System	06 Mar 2021 13:09:00
User entered 'No (N)'	System	06 Mar 2021 13:09:00

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2021-03-06T08:08:58-05:00', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '45c7f023-9074-48fa-a572-b612a1329ca6'	System	06 Mar 2021 13:09:00
User entered '06 Mar 2021 08:08:58'	System	06 Mar 2021 13:09:00

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[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 (c00cae2bfb0fab6f)', Time: '2021-03-13T07:39:09-05:00', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '2ee0f74b-4cda-44f1-9c7d-98691cdfdadf'	System	13 Mar 2021 12:39:25
User entered 'No (N)'	System	13 Mar 2021 12:39:25

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

Have you been exposed to someone with 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 (c00cae2bfb0fab6f)', Time: '2021-03-13T07:39:15-05:00', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '2ee0f74b-4cda-44f1-9c7d-98691cdfdadf'	System	13 Mar 2021 12:39:25
User entered 'No (N)'	System	13 Mar 2021 12:39:25

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2021-03-13T07:39:22-05:00', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '2ee0f74b-4cda-44f1-9c7d-98691cdfdadf' User entered '13 Mar 2021 07:39:22'	System	13 Mar 2021 12:39:25
	System	13 Mar 2021 12:39:25

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[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 (c00cae2bfb0fab6f)', Time: '2021-03-20T15:31:30-04:00', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '9aeaac58-bc1d-427e-8add-3c420d64f102'	System	20 Mar 2021 19:31:46
User entered 'No (N)'	System	20 Mar 2021 19:31:46

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

Have you been exposed to someone with 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 (c00cae2bfb0fab6f)', Time: '2021-03-20T15:31:34-04:00', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '9aeaac58-bc1d-427e-8add-3c420d64f102'	System	20 Mar 2021 19:31:46
User entered 'No (N)'	System	20 Mar 2021 19:31:46

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2021-03-20T15:31:40-04:00', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '9aeaac58-bc1d-427e-8add-3c420d64f102'	System	20 Mar 2021 19:31:46
User entered '20 Mar 2021 15:31:40'	System	20 Mar 2021 19:31:46

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[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 (c00cae2bfb0fab6f)', Time: '2021-03-28T10:50:41-04:00', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'a8a9667e-3fbd-42f2-aff4-41206f8c640d'	System	28 Mar 2021 14:50:58
User entered 'No (N)'	System	28 Mar 2021 14:50:58

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

Have you been exposed to someone with 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 (c00cae2bfb0fab6f)', Time: '2021-03-28T10:50:45-04:00', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'a8a9667e-3fbd-42f2-aff4-41206f8c640d'	System	28 Mar 2021 14:50:58
User entered 'No (N)'	System	28 Mar 2021 14:50:58

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2021-03-28T10:50:52-04:00', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'a8a9667e-3fbd-42f2-aff4-41206f8c640d' User entered '28 Mar 2021 10:50:52'	System	28 Mar 2021 14:50:58
	System	28 Mar 2021 14:50:58

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[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 (c00cae2bfb0fab6f)', Time: '2021-04-03T08:41:02-04:00', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'f78676e4-90ce-4968-a99f-5d35739898ce' User entered 'No (N)'	System	03 Apr 2021 12:41:16
	System	03 Apr 2021 12:41:16

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

Have you been exposed to someone with 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 (c00cae2bfb0fab6f)', Time: '2021-04-03T08:41:07-04:00', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'f78676e4-90ce-4968-a99f-5d35739898ce'	System	03 Apr 2021 12:41:16
User entered 'No (N)'	System	03 Apr 2021 12:41:16

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2021-04-03T08:41:12-04:00', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'f78676e4-90ce-4968-a99f-5d35739898ce'	System	03 Apr 2021 12:41:16
User entered '03 Apr 2021 08:41:12'	System	03 Apr 2021 12:41:16

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[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 (c00cae2bfb0fab6f)', Time: '2021-04-11T08:51:23-04:00', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '4b5c3a20-46dc-464d-863b-a640c5067b89'	System	11 Apr 2021 12:52:16
User entered 'Yes (Y)'	System	11 Apr 2021 12:52:16

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

Have you been exposed to someone with 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 (c00cae2bfb0fab6f)', Time: '2021-04-11T08:51:29-04:00', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '4b5c3a20-46dc-464d-863b-a640c5067b89'	System	11 Apr 2021 12:52:16
User entered 'No (N)'	System	11 Apr 2021 12:52:16

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[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 (c00cae2bfb0fab6f)', Time: '2021-04-11T08:51:34-04:00', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '4b5c3a20-46dc-464d-863b-a640c5067b89'	System	11 Apr 2021 12:52:16
User entered 'No (N)'	System	11 Apr 2021 12:52:16

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

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 (c00cae2bfb0fab6f)', Time: '2021-04-11T08:51:39-04:00', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '4b5c3a20-46dc-464d-863b-a640c5067b89'	System	11 Apr 2021 12:52:16
User entered 'Yes (Y)'	System	11 Apr 2021 12:52:16

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

Please 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 (c00cae2bfb0fab6f)', Time: '2021-04-11T08:51:53-04:00', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '4b5c3a20-46dc-464d-863b-a640c5067b89'	System	11 Apr 2021 12:52:16
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Apr 2021 12:52:16

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2021-04-11T08:52:05-04:00', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '4b5c3a20-46dc-464d-863b-a640c5067b89'	System	11 Apr 2021 12:52:16
User entered '11 Apr 2021 08:52:05'	System	11 Apr 2021 12:52:16

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[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 (c00cae2bfb0fab6f)', Time: '2021-04-17T18:55:36-04:00', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'f45382c0-fcf6-47b7-a7b6-891011a714a8'	System	17 Apr 2021 22:55:47
User entered 'No (N)'	System	17 Apr 2021 22:55:47

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

Have you been exposed to someone with 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 (c00cae2bfb0fab6f)', Time: '2021-04-17T18:55:39-04:00', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'f45382c0-fcf6-47b7-a7b6-891011a714a8'	System	17 Apr 2021 22:55:47
User entered 'No (N)'	System	17 Apr 2021 22:55:47

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2021-04-17T18:55:43-04:00', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'f45382c0-fcf6-47b7-a7b6-891011a714a8'	System	17 Apr 2021 22:55:47
User entered '17 Apr 2021 18:55:43'	System	17 Apr 2021 22:55:47

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[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 (c00cae2bfb0fab6f)', Time: '2021-04-25T10:23:50-04:00', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'aff0ea38-3842-47bf-a4d4-cb0f2b00817f' User entered 'No (N)'	System	25 Apr 2021 14:24:03
	System	25 Apr 2021 14:24:03

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

Have you been exposed to someone with 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 (c00cae2bfb0fab6f)', Time: '2021-04-25T10:23:55-04:00', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'aff0ea38-3842-47bf-a4d4-cb0f2b00817f' User entered 'No (N)'	System	25 Apr 2021 14:24:03
	System	25 Apr 2021 14:24:03

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2021-04-25T10:24:00-04:00', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: 'aff0ea38-3842-47bf-a4d4-cb0f2b00817f' User entered '25 Apr 2021 10:24:00'	System	25 Apr 2021 14:24:03
	System	25 Apr 2021 14:24:03

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 03:17:44

US3202395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:17:44
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 03:17:44

US3202395

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:41:52

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 07:19:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2021-03-01T07:46:08-05:00', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '66f15cc7-1fbf-4729-9a02-5bba8a384556'	System	01 Mar 2021 12:46:18
User entered 'No (N)'	System	01 Mar 2021 12:46:18

US3202395

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:41:52

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:19:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c00cae2bfb0fab6f)', Time: '2021-03-01T07:46:18-05:00', User OID: 'PatientReportedOutcome (US3202395)', ODM File OID: '66f15cc7-1fbf-4729-9a02-5bba8a384556'	System	01 Mar 2021 12:46:18
User entered '01 Mar 2021 07:46:18'	System	01 Mar 2021 12:46:18

US3202395

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:55:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 18:15:46

US3202395

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:55:20
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 23SEP2020 is reported under Illness Visit 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) (4), (b) (6)	02 Feb 2021 11:15:58
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 23SEP2020 is reported under Illness Visit 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 'Why is a lab query under a safety call? also, subj was seen Sep 29 for illness. lab results are dated for Sep 29. Not sure what above query is regarding.' (Site from DM).	Teresa Deese (b) (4)	01 Feb 2021 18:35:00
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 23SEP2020 is reported under Illness Visit 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 12:43:43
User entered '3 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Dec 2020 15:13:52
User entered '2 Dec 2020'	(b) (4), (b) (6)	02 Dec 2020 18:15:46

US3202395

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:55:20
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:13:52
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	02 Dec 2020 18:15:46

US3202395

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:55:20
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:13:52
User entered 'Left a message'	(b) (4), (b) (6)	02 Dec 2020 18:15:46

US3202395

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:55:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 18:15:50

US3202395

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:54:13
User entered '1'	System	02 Dec 2020 18:15:50

US3202395

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:44:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	08 Mar 2021 21:29:05

US3202395

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:44:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '5 Jan 2021'	(b) (4) Teresa Deese (b) (4)	08 Mar 2021 21:29:05

US3202395

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:44:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Teresa Deese (b) (4)	08 Mar 2021 21:29:05

US3202395

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:44:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) Teresa Deese (b) (4)	08 Mar 2021 21:29:05

US3202395

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:44:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Teresa Deese (b) (4)	08 Mar 2021 21:30:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Dec 2020 00:42:26
Query 'Data is required. Please complete.' answered with 'entry error' (Site from System).	(b) (4), (b) (6)	03 Dec 2020 15:15:33
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Dec 2020 15:15:26
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	03 Dec 2020 15:15:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Dec 2020 15:14:02

US3202395

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:44:07
User entered '1'	System	08 Mar 2021 21:30:58
User entered empty.	System	03 Dec 2020 15:15:26
User entered '1'	System	03 Dec 2020 15:14:02

US3202395

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:44:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:49
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	08 Mar 2021 21:31:28

US3202395

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:44:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:49
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 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)	09 Mar 2021 16:23:20
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'PD noted. OOW' (Site from System).	Teresa Deese (b) (4)	08 Mar 2021 21:31:47
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	08 Mar 2021 21:31:28
User entered '9 Feb 2021'	Teresa Deese (b) (4)	08 Mar 2021 21:31:28

US3202395

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:44:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Teresa Deese (b) (4)	08 Mar 2021 21:31:28

US3202395

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:44:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:49
User entered empty.	(b) (4) Teresa Deese (b) (4)	08 Mar 2021 21:31:28

US3202395

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:44:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	08 Mar 2021 21:31:52

US3202395

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:44:07
User entered 'I'	System	08 Mar 2021 21:31:52

US3202395

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:44:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:49
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	08 Mar 2021 21:32:08

US3202395

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:44:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:49
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	09 Mar 2021 16:24:27
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'PD noted. OOW' (Site from System).	Teresa Deese (b) (4)	08 Mar 2021 21:32:21
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	08 Mar 2021 21:32:08
User entered '1 Mar 2021'	Teresa Deese (b) (4)	08 Mar 2021 21:32:08

US3202395

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:44:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Teresa Deese (b) (4)	08 Mar 2021 21:32:08

US3202395

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:44:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:49
User entered empty.	(b) (4) Teresa Deese (b) (4)	08 Mar 2021 21:32:08

US3202395

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:44:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:49
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	08 Mar 2021 21:32:26

US3202395

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:44:07
User entered '1'	System	08 Mar 2021 21:32:26

US3202395

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:49
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 21:52:25

US3202395

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:52

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:49
User entered '5 Apr 2021'	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 21:52:25

US3202395

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:52

[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 22:14:28
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:49
User entered 'Clinic (Clinic)'	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 21:52:25

US3202395

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
User entered 'VISIT4'	System	05 Apr 2021 21:52:25

US3202395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:49
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 21:52:31

US3202395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:49
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 21:52:31

US3202395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:49
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 21:52:31

US3202395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
User entered empty.	System	05 Apr 2021 21:52:31

US3202395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:49
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 21:52:31

US3202395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:49
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 21:52:31

US3202395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:49
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 21:52:31

US3202395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:49
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 21:52:31

US3202395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
User entered empty.	System	05 Apr 2021 21:52:31

US3202395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:49
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 21:52:31

US3202395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
User entered empty.	System	05 Apr 2021 21:52:31

US3202395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:49
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 21:52:31

US3202395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
User entered empty.	System	05 Apr 2021 21:52:31

US3202395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:49
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 21:52:31

US3202395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
User entered empty.	System	05 Apr 2021 21:52:31

US3202395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28

US3202395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28

US3202395

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:49
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 21:52:34

US3202395

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:49
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 21:52:34

US3202395

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:49
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 21:52:42

US3202395

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:52

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:49
User entered '5 Apr 2021'	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 21:52:42

US3202395

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:52

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:49
User entered '10:46'	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 21:52:42

US3202395

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
User entered '5 Apr 2021 10:46'	System	05 Apr 2021 21:52:42

US3202395

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:49
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 21:52:44

US3202395

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:28
User entered '1'	System	05 Apr 2021 21:52:44

US3202395

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:41:52

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:19:33
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '29 Sep 2020'	(b) (4) zackery harmon (b) (4)	23 Mar 2021 15:45:46
	(b) (4)	

US3202395

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:41:52

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:19:33
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '09:30'	(b) (4) zackery harmon (b) (4)	23 Mar 2021 15:45:46
	(b) (4)	

US3202395

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:41:52

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:19:33
User entered '29 Sep 2020 09:30'	System	23 Mar 2021 15:45:46

US3202395

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:41:52

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:19:33
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4) zackery harmon (b) (4)	23 Mar 2021 15:45:46

US3202395

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:41:52

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:19:33
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	23 Mar 2021 15:45:46
	(b) (4)	

US3202395

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:41:52

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:19:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '29 Sep 2020'	(b) (4) zackery harmon (b) (4)	23 Mar 2021 15:46:18
	(b) (4)	

US3202395

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:41:52

[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 03:19:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	23 Mar 2021 15:46:18
	(b) (4)	

US3202395

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:41:52

[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 03:19:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	23 Mar 2021 15:46:18
	(b) (4)	

US3202395

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:41:52

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:19:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '29 Sep 2020'	(b) (4) zackery harmon (b) (4)	23 Mar 2021 15:46:18
	(b) (4)	

US3202395

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:41:52

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:19:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Nasopharyngeal Swab (Nasopharyngeal zackery harmon Swab)'	(b) (4)	23 Mar 2021 15:46:18

US3202395

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:41:52

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:19:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) zackery harmon (b) (4)	23 Mar 2021 15:46:18
	(b) (4)	

US3202395

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:41:52

[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 03:19:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	23 Mar 2021 15:46:18
	(b) (4)	

US3202395

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:41:52

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:19:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) zackery harmon (b) (4)	23 Mar 2021 15:46:18
	(b) (4)	

US3202395

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:41:52

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:19:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) zackery harmon (b) (4)	23 Mar 2021 15:46:18
	(b) (4)	

US3202395

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:41:52

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:19:45
User entered '0'	System	23 Mar 2021 15:46:18

US3202395

Folder: Covid-19 Assessment 29 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:41:52

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:19:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	23 Mar 2021 15:46:25
	(b) (4)	

US3202395

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:41:52

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	12 Nov 2020 18:49:04

US3202395

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:41:52

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:49:04

US3202395

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:41:52

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:49:04

US3202395

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:41:52

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	12 Nov 2020 18:49:04

US3202395

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:41:52

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:49:04

US3202395

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:41:52

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:49:04

US3202395

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:41:52

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	12 Nov 2020 18:49:04

US3202395

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:41:52

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:49:04

US3202395

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:41:52

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:49:04

US3202395

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:41:52

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	12 Nov 2020 18:49:04

US3202395

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:41:52

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:49:04

US3202395

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:41:52

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:49:04

US3202395

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:41:52

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	12 Nov 2020 18:49:04

US3202395

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:41:52

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:49:04

US3202395

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:41:52

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:49:04

US3202395

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:41:52

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	12 Nov 2020 18:49:04

US3202395

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:41:52

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:49:04

US3202395

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:41:52

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:49:04

US3202395

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:41:52

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	12 Nov 2020 18:49:04

US3202395

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:41:52

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:49:04

US3202395

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:41:52

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:49:04

US3202395

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 21:37:00

US3202395

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:52

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 29-SEP-2020 is reported under Illness Visit Day 1 in PPD portal; however, swab sample for 29-SEP-2020 is missing in EDC. Kindly confirm if swab sample was collected, if yes, consider initiating Covid -19 Assessment eCRF for 29-SEP-2020 and update swab data in COVID Diagnostic Test eCRF, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 04:29:44
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 29-SEP-2020 is reported under Illness Visit Day 1 in PPD portal; however, swab sample for 29-SEP-2020 is missing in EDC. Kindly confirm if swab sample was collected, if yes, consider initiating Covid -19 Assessment eCRF for 29-SEP-2020 and update swab data in COVID Diagnostic Test eCRF, else clarify.' answered with 'updated' (Site from DM).	zackery harmon (b) (4) (b) (4)	23 Mar 2021 15:46:35
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 29-SEP-2020 is reported under Illness Visit Day 1 in PPD portal; however, swab sample for 29-SEP-2020 is missing in EDC. Kindly confirm if swab sample was collected, if yes, consider initiating Covid -19 Assessment eCRF for 29-SEP-2020 and update swab data in COVID Diagnostic Test eCRF, else clarify.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 06:15:38
User entered '29 Sep 2020'	(b) (4), (b) (6)	17 Dec 2020 21:37:00

US3202395

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:52

[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 18:26:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 21:37:00

US3202395

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
User entered 'SICKD1'	System	17 Dec 2020 21:37:00

US3202395

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	16 Feb 2021 21:54:37

US3202395

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '29 Sep 2020'	(b) (4) Teresa Deese (b) (4)	16 Feb 2021 21:54:37

US3202395

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '09:40'	(b) (4) Teresa Deese (b) (4)	16 Feb 2021 21:54:37

US3202395

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
User entered '29 Sep 2020 09:40'	System	16 Feb 2021 21:54:37

US3202395

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '159' cm	(b) (4) Teresa Deese (b) (4)	16 Feb 2021 21:54:37
DataPoint set to visible.	System	17 Dec 2020 21:37:00

US3202395

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '56.6' kg	(b) (4) Teresa Deese (b) (4)	16 Feb 2021 21:54:37
DataPoint set to visible.	System	17 Dec 2020 21:37:00

US3202395

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User closed query 'Per CDM: Please update 'Temperature' as per the required format (xxx.x)' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:42:48
Query 'Per CDM: Please update 'Temperature' as per the required format (xxx.x)' answered with 'done' (Site from DM).	Teresa Deese (b) (4)	02 Mar 2021 16:06:20
User entered '37.0' C reason for change: Data Entry Error	Teresa Deese (b) (4)	02 Mar 2021 16:06:15
User opened query 'Per CDM: Please update 'Temperature' as per the required format (xxx.x)' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 11:52:17
User entered '37' C	Teresa Deese (b) (4)	16 Feb 2021 21:54:37

US3202395

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Oral (Oral)'	(b) (4) Teresa Deese (b) (4)	16 Feb 2021 21:54:37

US3202395

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) Teresa Deese (b) (4)	16 Feb 2021 21:54:37

US3202395

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '82'	(b) (4) Teresa Deese (b) (4)	16 Feb 2021 21:54:37

US3202395

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
User entered 'bpm'	System	16 Feb 2021 21:54:37

US3202395

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '14'	(b) (4) Teresa Deese (b) (4)	16 Feb 2021 21:54:37

US3202395

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
User entered 'breaths/min'	System	16 Feb 2021 21:54:37

US3202395

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '106'	(b) (4) Teresa Deese (b) (4)	16 Feb 2021 21:54:37

US3202395

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
User entered 'mmHg'	System	16 Feb 2021 21:54:37

US3202395

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '78'	(b) (4) Teresa Deese (b) (4)	16 Feb 2021 21:54:37

US3202395

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
User entered 'mmHg'	System	16 Feb 2021 21:54:37

US3202395

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57

US3202395

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57

US3202395

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:52

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	16 Feb 2021 21:54:48

US3202395

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '29 Sep 2020'	(b) (4) Teresa Deese (b) (4)	16 Feb 2021 21:54:48

US3202395

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 15:41:52

[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 18:26:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 19:39:30

US3202395

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 15:41:52

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re- Query: Thank you for the response, Please confirm the correct visit label in the response for the SARS-CoV-2 serum sample dated 29 SEP 2020 as it is recorded under illness Visit Day 1 in EDC and Convalescence Visit Day 28 visit in PPD Central lab.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 10:04:50
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re- Query: Thank you for the response, Please confirm the correct visit label in the response for the SARS-CoV-2 serum sample dated 29 SEP 2020 as it is recorded under illness Visit Day 1 in EDC and Convalescence Visit Day 28 visit in PPD Central lab.' answered with 'this is for illness vs. done 29 Sep. THERE WAS NO CONVASCLESCENT VS.' (Site from DM).	Teresa Deese (b) (4)	29 Mar 2021 19:21:17
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re- Query: Thank you for the response, Please confirm the correct visit label in the response for the SARS-CoV-2 serum sample dated 29 SEP 2020 as it is recorded under illness Visit Day 1 in EDC and Convalescence Visit Day 28 visit in PPD Central lab.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 08:21:26
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2: There is a duplicate entry for the SARS-CoV-2 sample dated 29 SEP 2020 as it is recorded under Convalescence Visit Day 28 and illness Visit Day1 in EDC for illness Visit (1), Please review and update appropriately.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 08:13:07
Query 'Per GCL Lab Reconciliation: SARS-CoV-2: There is a duplicate entry for the SARS-CoV-2 sample dated 29 SEP 2020 as it is recorded under Convalescence Visit Day 28 and illness Visit Day1 in EDC for illness Visit (1), Please review and update appropriately.' answered with 'updated' (Site from DM).	zackery harmon (b) (4) (b) (4)	22 Mar 2021 16:16:44

US3202395

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 15:41:52

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2: There is a duplicate entry for the SARS-CoV-2 sample dated 29 SEP 2020 as it is recorded under Convalescence Visit Day 28 and illness Visit Day1 in EDC for illness Visit (1), Please review and update appropriately.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 07:41:21
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2: Sample dated 29 SEP 2020 is reported under illness visit Day 1 in EDC, however the same SARS-CoV-2 serum sample is reported in the Convalescence Visit Day 28 in PPD Central lab. 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)	17 Feb 2021 10:32:24
Query 'Per GCL Lab Reconciliation: SARS-CoV-2: Sample dated 29 SEP 2020 is reported under illness visit Day 1 in EDC, however the same SARS-CoV-2 serum sample is reported in the Convalescence Visit Day 28 in PPD Central lab. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'seen for illness vs on Sep 29' (Site from DM).	Teresa Deese (b) (4)	16 Feb 2021 21:52:41
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2: Sample dated 29 SEP 2020 is reported under illness visit Day 1 in EDC, however the same SARS-CoV-2 serum sample is reported in the Convalescence Visit Day 28 in PPD Central lab. 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)	09 Feb 2021 06:03:24
User entered '29 Sep 2020'	(b) (4), (b) (6)	18 Dec 2020 19:39:30

US3202395

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	zackery harmon (b) (4)	22 Mar 2021 16:14:18
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 18:17:46

US3202395

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:52

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered empty; reason for change Data Entry Error	zackery harmon (b) (4)	22 Mar 2021 16:14:18
	(b) (4)	
User entered '29 Sep 2020'	(b) (4), (b) (6)	12 Nov 2020 18:17:46

US3202395

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:52

[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 16:13:18
	(b) (4)	
User entered empty; reason for change Data Entry Error	zackery harmon (b) (4)	22 Mar 2021 16:14:18
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	12 Nov 2020 18:17:46

US3202395

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:52

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	12 Nov 2020 18:17:46

US3202395

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 12:44:35
Query 'Data is required. Please complete.' answered with 'subject didn't come in' (Site from System).	zackery harmon (b) (4)	22 Mar 2021 16:14:54
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Mar 2021 16:14:48
User entered empty; reason for change Data Entry Error	System	22 Mar 2021 16:14:48
User entered 'Yes (Y)'	zackery harmon (b) (4)	22 Mar 2021 16:14:48
	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 18:20:38

US3202395

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User closed query 'Per CDM: Date of COVALESCENCE VISIT DAY 28 (1) is same as ILLNESS VISIT 1. Please review for potential duplicate visit and remove data/inactivate page accordingly, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 12:44:38
Query 'Per CDM: Date of COVALESCENCE VISIT DAY 28 (1) is same as ILLNESS VISIT 1. Please review for potential duplicate visit and remove data/inactivate page accordingly, else clarify.' answered with 'updated needs inactivated' (Site from DM).	zackery harmon (b) (4) (b) (4)	22 Mar 2021 16:15:36
User entered empty; reason for change Data Entry Error	zackery harmon (b) (4) (b) (4)	22 Mar 2021 16:14:48
User opened query 'Per CDM: Date of COVALESCENCE VISIT DAY 28 (1) is same as ILLNESS VISIT 1. Please review for potential duplicate visit and remove data/inactivate page accordingly, else clarify.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 06:05:13
User entered '29 Sep 2020'	(b) (4), (b) (6)	12 Nov 2020 18:20:38

US3202395

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered empty; reason for change Data Entry Error	zackery harmon (b) (4)	22 Mar 2021 16:14:48
	(b) (4)	
User entered '09:40'	(b) (4), (b) (6)	12 Nov 2020 18:20:38

US3202395

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
User entered empty.	System	22 Mar 2021 16:14:48
User entered '29 Sep 2020 09:40'	System	12 Nov 2020 18:20:38

US3202395

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered empty; reason for change Data Entry Error	zackery harmon (b) (4)	22 Mar 2021 16:14:48
	(b) (4)	
User entered '36.9' C	(b) (4), (b) (6)	12 Nov 2020 18:20:38

US3202395

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered empty; reason for change Data Entry Error	zackery harmon (b) (4)	22 Mar 2021 16:14:48
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	12 Nov 2020 18:20:38

US3202395

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:20:38

US3202395

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered empty; reason for change Data Entry Error	zackery harmon (b) (4)	22 Mar 2021 16:14:48
	(b) (4)	
User entered '82'	(b) (4), (b) (6)	12 Nov 2020 18:20:38

US3202395

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Mar 2021 16:14:48
User entered 'bpm'	System	12 Nov 2020 18:20:38

US3202395

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered empty; reason for change Data Entry Error	zackery harmon (b) (4)	22 Mar 2021 16:14:48
	(b) (4)	
User entered '14'	(b) (4), (b) (6)	12 Nov 2020 18:20:38

US3202395

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Mar 2021 16:14:48
User entered 'breaths/min'	System	12 Nov 2020 18:20:38

US3202395

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered empty; reason for change Data Entry Error	zackery harmon (b) (4)	22 Mar 2021 16:14:48
	(b) (4)	
User entered '106'	(b) (4), (b) (6)	12 Nov 2020 18:20:38

US3202395

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Mar 2021 16:14:48
User entered 'mmHg'	System	12 Nov 2020 18:20:38

US3202395

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered empty; reason for change Data Entry Error	zackery harmon (b) (4)	22 Mar 2021 16:14:48
	(b) (4)	
User entered '78'	(b) (4), (b) (6)	12 Nov 2020 18:20:38

US3202395

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Mar 2021 16:14:48
User entered 'mmHg'	System	12 Nov 2020 18:20:38

US3202395

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 12:44:28
Query 'Data is required. Please complete.' answered with 'updated' (Site from System).	zackery harmon (b) (4)	22 Mar 2021 16:15:53
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Mar 2021 16:15:43
User entered empty; reason for change Data Entry Error	System	22 Mar 2021 16:15:43
User entered 'Yes (Y)'	zackery harmon (b) (4)	22 Mar 2021 16:15:43
	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 18:21:27

US3202395

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered empty; reason for change Data Entry Error	zackery harmon (b) (4)	22 Mar 2021 16:15:43
	(b) (4)	
User entered '29 Sep 2020'	(b) (4), (b) (6)	12 Nov 2020 18:21:27

US3202395

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 15:41:52

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 16:13:18
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	23 Mar 2021 12:44:19
User opened query 'Data is required. Please complete.' (Site from System).	zackery harmon (b) (4)	22 Mar 2021 16:16:07
User entered empty; reason for change Data Entry Error	(b) (4)	
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Please consider updating the "Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?" field appropriately as the date of collection field updated to blank OR else clarify. Thank you.' (Site from DM).	System	22 Mar 2021 16:16:00
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Please consider updating the "Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?" field appropriately as the date of collection field updated to blank OR else clarify. Thank you.' answered with 'done' (Site from DM).	zackery harmon (b) (4)	22 Mar 2021 16:16:00
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Please consider updating the "Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?" field appropriately as the date of collection field updated to blank OR else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Please consider updating the "Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?" field appropriately as the date of collection field updated to blank OR else clarify. Thank you.'	Teresa Deese (b) (4)	01 Feb 2021 18:36:19
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Please consider updating the "Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?" field appropriately as the date of collection field updated to blank OR else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Please consider updating the "Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?" field appropriately since the date of collection field updated to blank. Thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	

US3202395

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 15:41:52

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User opened query ' Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Please consider updating the "Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?" field appropriately since the date of collection field updated to blank. Thank you. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 06:11:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 18:23:43

US3202395

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 15:41:52

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered empty; reason for change Data Entry Error	zackery harmon (b) (4)	22 Mar 2021 16:16:00
	(b) (4)	
User entered '29 Sep 2020' reason for change: Data Entry Error	Teresa Deese (b) (4)	01 Feb 2021 18:36:12
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Please consider updating date of collection field.' canceled (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 06:07:24
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Please consider updating date of collection field.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 05:54:41
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: As Per response " illness visit day 28 accession number: 1F60FKY" , Please update the SARS-CoV-2 sample dated 29 SEP 2020 on illness Visit Day 1 in the EDC and also please keep the Convalescent SARS-CoV-2 serum sample form Blank on this page. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 08:06:53
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: As Per response " illness visit day 28 accession number: 1F60FKY" , Please update the SARS-CoV-2 sample dated 29 SEP 2020 on illness Visit Day 1 in the EDC and also please keep the Convalescent SARS-CoV-2 serum sample form Blank on this page. Thank you.' answered with 'CORRECTED. DATE OF SARS-COV-2 SERUM SAMPLE REMOVED FROM THIS PAGE AS DIRECTED PER QUERY.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 19:40:48
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 19:39:50
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: As Per response " illness visit day 28 accession number: 1F60FKY" , Please update the SARS-CoV-2 sample dated 29 SEP 2020 on illness Visit Day 1 in the EDC and also please keep the Convalescent SARS-CoV-2 serum sample form Blank on this page. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 06:37:31

US3202395

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 15:41:52

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re- Query: Thank you for the response, Please confirm the correct visit label in the response for the SARS-CoV-2 serum sample dated 29 SEP 2020 as it is recorded under Convalescence Visit Day 28 in EDC and illness Visit Day 1 in PPD Central lab.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 06:37:31
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re- Query: Thank you for the response, Please confirm the correct visit label in the response for the SARS-CoV-2 serum sample dated 29 SEP 2020 as it is recorded under Convalescence Visit Day 28 in EDC and illness Visit Day 1 in PPD Central lab.' answered with 'illness visit day 28 accession number: 1F60FKY ' (Site from DM).	zackery harmon (b) (4) (b) (4)	15 Dec 2020 21:26:28
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re- Query: Thank you for the response, Please confirm the correct visit label in the response for the SARS-CoV-2 serum sample dated 29 SEP 2020 as it is recorded under Convalescence Visit Day 28 in EDC and illness Visit Day 1 in PPD Central lab.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 06:52:24
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 29 SEP 2020 is reported under Convalescence Visit Day 28 in EDC, however the same SARS-CoV-2 serum sample is reported in the illness visit Day 1 in PPD Central lab. 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)	23 Nov 2020 08:57:21
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 29 SEP 2020 is reported under Convalescence Visit Day 28 in EDC, however the same SARS-CoV-2 serum sample is reported in the illness visit Day 1 in PPD Central lab. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'Done. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 15:31:05

US3202395

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 15:41:52

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 29 SEP 2020 is reported under Convalescence Visit Day 28 in EDC, however the same SARS-CoV-2 serum sample is reported in the illness visit Day 1 in PPD Central lab. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM). User entered '29 Sep 2020'	(b) (4), (b) (6) [REDACTED] [REDACTED]	18 Nov 2020 06:59:46
	(b) (4), (b) (6) [REDACTED]	12 Nov 2020 18:23:43

US3202395

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

Form: Visit Date

Generated On: 09 Jun 2021 15:41:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:36:49

US3202395

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

Form: Visit Date

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '1 Feb 2021'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:36:49

US3202395

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

Form: Visit Date

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Clinic (Clinic)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:36:49

US3202395

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

Form: Visit Date

Generated On: 09 Jun 2021 15:41:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User entered 'UNBLND_DECIDE'	System	01 Feb 2021 18:36:49

US3202395

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

Form: Unblinding

Generated On: 09 Jun 2021 15:41:52

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '1 Feb 2021'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:37:05

US3202395

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

Form: Unblinding

Generated On: 09 Jun 2021 15:41:52

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '0'	(b) (4) Teresa Deese (b) (4)	08 Mar 2021 21:29:54
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:30:41

US3202395

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

Form: Unblinding

Generated On: 09 Jun 2021 15:41:52

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:37:05

US3202395

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

Form: Unblinding

Generated On: 09 Jun 2021 15:41:52

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) Teresa Deese (b) (4)	08 Mar 2021 21:29:54
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:30:41

US3202395

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

Form: Unblinding

Generated On: 09 Jun 2021 15:41:52

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '1 Feb 2021'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:37:05

US3202395

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

Form: Unblinding

Generated On: 09 Jun 2021 15:41:52

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Placebo (Placebo)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:37:05

US3202395

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

Form: Unblinding

Generated On: 09 Jun 2021 15:41:52

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Placebo (Placebo)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:37:05

US3202395

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

Form: Unblinding

Generated On: 09 Jun 2021 15:41:52

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Placebo (Placebo)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:37:05

US3202395

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

Form: Unblinding

Generated On: 09 Jun 2021 15:41:52

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:37:05

US3202395

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

Form: Unblinding

Generated On: 09 Jun 2021 15:41:52

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User entered '1'	System	01 Feb 2021 18:37:05

US3202395

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

Form: Unblinding

Generated On: 09 Jun 2021 15:41:52

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User entered '1'	System	01 Feb 2021 18:37:05

US3202395

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:41:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:38:00

US3202395

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:41:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:38:00

US3202395

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:41:52

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User entered empty.	System	01 Feb 2021 18:38:00
DataPoint set to visible.	System	01 Feb 2021 18:37:05

US3202395

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:41:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:38:00

US3202395

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:41:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:38:00

US3202395

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:41:52

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User entered empty.	System	01 Feb 2021 18:38:00
DataPoint set to visible.	System	01 Feb 2021 18:37:05

US3202395

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User accepted default value 'Pre-Dose (PREDOSE)'	Teresa Deese (b) (4)	01 Feb 2021 18:38:00

US3202395

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:38:00

US3202395

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '1 Feb 2021'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:38:00

US3202395

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '12:25'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:38:00

US3202395

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User entered '1 Feb 2021 12:25'	System	01 Feb 2021 18:38:00

US3202395

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '36.8' C	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:38:00

US3202395

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Oral (Oral)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:38:00

US3202395

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:38:00

US3202395

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '72'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:38:00

US3202395

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User entered 'bpm'	System	01 Feb 2021 18:38:00

US3202395

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '18'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:38:00

US3202395

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User entered 'breaths/min'	System	01 Feb 2021 18:38:00

US3202395

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '142'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:38:00

US3202395

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User entered 'mmHg'	System	01 Feb 2021 18:38:00

US3202395

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '82'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:38:00

US3202395

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User entered 'mmHg'	System	01 Feb 2021 18:38:00

US3202395

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:41:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:38:00

US3202395

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:41:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:38:00

US3202395

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:41:52

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User entered empty.	System	01 Feb 2021 18:38:00
DataPoint set to visible.	System	01 Feb 2021 18:37:05

US3202395

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User accepted default value 'Post-Dose (POSTDOSE)'	Teresa Deese (b) (4)	01 Feb 2021 18:38:43

US3202395

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:38:43

US3202395

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '1 Feb 2021'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:38:43

US3202395

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '13:20'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:38:43

US3202395

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User entered '1 Feb 2021 13:20'	System	01 Feb 2021 18:38:43

US3202395

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	04 Feb 2021 10:44:35
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.'	Teresa Deese (b) (4)	01 Feb 2021 18:38:49
answered with 'NCS' (Site from System).		
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	01 Feb 2021 18:38:43
User entered '35.8' C	Teresa Deese (b) (4)	01 Feb 2021 18:38:43

US3202395

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Oral (Oral)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:38:43

US3202395

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:38:43

US3202395

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '70'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:38:43

US3202395

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User entered 'bpm'	System	01 Feb 2021 18:38:43

US3202395

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '16'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:38:43

US3202395

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User entered 'breaths/min'	System	01 Feb 2021 18:38:43

US3202395

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '126'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:38:43

US3202395

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User entered 'mmHg'	System	01 Feb 2021 18:38:43

US3202395

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '87'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:38:43

US3202395

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User entered 'mmHg'	System	01 Feb 2021 18:38:43

US3202395

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:39:04

US3202395

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:39:04

US3202395

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

Form: Exposure

Generated On: 09 Jun 2021 15:41:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:39:18

US3202395

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

Form: Exposure

Generated On: 09 Jun 2021 15:41:52

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:39:18

US3202395

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

Form: Exposure

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:39:18

US3202395

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

Form: Exposure

Generated On: 09 Jun 2021 15:41:52

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User entered 'mRNA-1273'	System	01 Feb 2021 18:39:18
DataPoint set to visible.	System	01 Feb 2021 18:37:05

US3202395

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

Form: Exposure

Generated On: 09 Jun 2021 15:41:52

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '1 Feb 2021'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:39:18

US3202395

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

Form: Exposure

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '12:34'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:39:18

US3202395

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

Form: Exposure

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User entered '1 Feb 2021 12:34'	System	01 Feb 2021 18:39:18

US3202395

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

Form: Exposure

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:39:18

US3202395

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

Form: Exposure

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User entered 'ONCE'	System	01 Feb 2021 18:39:18

US3202395

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

Form: Exposure

Generated On: 09 Jun 2021 15:41:52

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User entered 'INTRAMUSCULAR'	System	01 Feb 2021 18:39:18

US3202395

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:39:28

US3202395

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:52

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '1 Feb 2021'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:39:28

US3202395

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:52

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '12:29'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:39:28

US3202395

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User entered '1 Feb 2021 12:29'	System	01 Feb 2021 18:39:28

US3202395

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:41:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:39:38

US3202395

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:41:52

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '1 Feb 2021'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:39:38

US3202395

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:41:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '12:24'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:39:38

US3202395

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User entered '1 Feb 2021 12:24'	System	01 Feb 2021 18:39:38

US3202395

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

Form: Continuing

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:39:43

US3202395

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

Form: Continuing

Generated On: 09 Jun 2021 15:41:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:05:31
User entered '1'	System	01 Feb 2021 18:39:43

US3202395

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:49
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	09 Feb 2021 16:52:36

US3202395

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:49
User entered '9 Feb 2021'	(b) (4) Lilian Nukuna (b) (4)	09 Feb 2021 16:52:36

US3202395

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lilian Nukuna (b) (4)	09 Feb 2021 16:52:36

US3202395

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:49
User entered empty.	(b) (4) Lilian Nukuna (b) (4)	09 Feb 2021 16:52:36
	(b) (4)	

US3202395

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:49
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	09 Feb 2021 16:52:42

US3202395

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User entered '1'	System	09 Feb 2021 16:52:42

US3202395

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:52

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User entered '1'	System	09 Feb 2021 16:52:42
DataPoint set to visible.	System	09 Feb 2021 16:52:42

US3202395

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 16:07:58

US3202395

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '1 Mar 2021'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 16:07:58

US3202395

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Clinic (Clinic)'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 16:07:58

US3202395

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User entered 'OLD29'	System	02 Mar 2021 16:07:58

US3202395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User accepted default value 'Pre-Dose (PREDOSE)'	Teresa Deese (b) (4)	02 Mar 2021 16:08:37

US3202395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 16:08:37

US3202395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '1 Mar 2021'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 16:08:37

US3202395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '13:17'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 16:08:37

US3202395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User entered '1 Mar 2021 13:17'	System	02 Mar 2021 16:08:37

US3202395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '36.9' C	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 16:08:37

US3202395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Oral (Oral)'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 16:08:37

US3202395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 16:08:37

US3202395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '65'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 16:08:37

US3202395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User entered 'bpm'	System	02 Mar 2021 16:08:37

US3202395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '16'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 16:08:37

US3202395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User entered 'breaths/min'	System	02 Mar 2021 16:08:37

US3202395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '110'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 16:08:37

US3202395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User entered 'mmHg'	System	02 Mar 2021 16:08:37

US3202395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '63'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 16:08:37

US3202395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User entered 'mmHg'	System	02 Mar 2021 16:08:37

US3202395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User accepted default value 'Post-Dose (POSTDOSE)'	Teresa Deese (b) (4)	02 Mar 2021 16:09:09

US3202395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 16:09:09

US3202395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '1 Mar 2021'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 16:09:09

US3202395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '13:57'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 16:09:09

US3202395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User entered '1 Mar 2021 13:57'	System	02 Mar 2021 16:09:09

US3202395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '36.9' C	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 16:09:09

US3202395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Oral (Oral)'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 16:09:09

US3202395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 16:09:09

US3202395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '76'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 16:09:09

US3202395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User entered 'bpm'	System	02 Mar 2021 16:09:09

US3202395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '14'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 16:09:09

US3202395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User entered 'breaths/min'	System	02 Mar 2021 16:09:09

US3202395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '104'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 16:09:09

US3202395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User entered 'mmHg'	System	02 Mar 2021 16:09:09

US3202395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '74'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 16:09:09

US3202395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User entered 'mmHg'	System	02 Mar 2021 16:09:09

US3202395

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 16:09:14

US3202395

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 16:09:14

US3202395

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 16:09:32

US3202395

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:52

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 16:09:32

US3202395

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 16:09:32

US3202395

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:52

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User entered 'mRNA-1273'	System	02 Mar 2021 16:09:32
DataPoint set to visible.	System	09 Feb 2021 16:52:42

US3202395

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '1 Mar 2021'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 16:09:32

US3202395

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '13:27'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 16:09:32

US3202395

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User entered '1 Mar 2021 13:27'	System	02 Mar 2021 16:09:32

US3202395

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 16:09:32

US3202395

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User entered 'ONCE'	System	02 Mar 2021 16:09:32

US3202395

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User entered 'INTRAMUSCULAR'	System	02 Mar 2021 16:09:32

US3202395

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 16:09:37

US3202395

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User entered '1'	System	02 Mar 2021 16:09:37

US3202395

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:49
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	09 Mar 2021 22:13:36
	(b) (4)	

US3202395

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:49
User entered '9 Mar 2021'	(b) (4) Lilian Nukuna (b) (4)	09 Mar 2021 22:13:36

US3202395

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lilian Nukuna (b) (4)	09 Mar 2021 22:13:36

US3202395

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:49
User entered empty.	(b) (4) Lilian Nukuna (b) (4)	09 Mar 2021 22:13:36
	(b) (4)	

US3202395

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:49
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	09 Mar 2021 22:13:42

US3202395

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:49:04
User entered '1'	System	09 Mar 2021 22:13:42

US3202395

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:52:56

US3202395

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered '5 Apr 2021'	Erica Osmundsen (b) (4)	05 Apr 2021 21:52:56

US3202395

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:52

[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 16:13:18
	(b) (4)	
User entered 'Clinic (Clinic)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:52:56
	(b) (4)	
	(b) (4)	

US3202395

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:52

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	05 Apr 2021 21:52:56

US3202395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:53:00

US3202395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Apr 2021 21:53:00

US3202395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Apr 2021 21:53:00
	(b) (4)	
	(b) (4)	

US3202395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 21:53:00

US3202395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Apr 2021 21:53:00
	(b) (4)	
	(b) (4)	

US3202395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Apr 2021 21:53:00
	(b) (4)	
	(b) (4)	

US3202395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Apr 2021 21:53:00

US3202395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Apr 2021 21:53:00
	(b) (4)	
	(b) (4)	

US3202395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 21:53:00

US3202395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Apr 2021 21:53:00
	(b) (4)	
	(b) (4)	

US3202395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 21:53:00

US3202395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Apr 2021 21:53:00

US3202395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 21:53:00

US3202395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Apr 2021 21:53:00
	(b) (4)	
	(b) (4)	

US3202395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 21:53:00

US3202395

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:53:03

US3202395

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Apr 2021 21:53:03
	(b) (4)	
	(b) (4)	

US3202395

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:53:27
	(b) (4)	
	(b) (4)	

US3202395

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:52

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered '5 Apr 2021'	Erica Osmundsen (b) (4)	05 Apr 2021 21:53:27

US3202395

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:52

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered '10:46'	Erica Osmundsen (b) (4)	05 Apr 2021 21:53:27
	(b) (4)	
	(b) (4)	

US3202395

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
User entered '5 Apr 2021 10:46'	System	05 Apr 2021 21:53:27

US3202395

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:41:52

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:31:32
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 2 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)	21 Apr 2021 15:31:07
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 2 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)	21 Apr 2021 15:31:05
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 2 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 'ENTERED' (Site from DM).	Erica Osmundsen (b) (4)	20 Apr 2021 17:23:12
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 2 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 'ENTERED' (Site from DM).	Erica Osmundsen (b) (4)	20 Apr 2021 17:23:09

US3202395

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:41:52

[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 2 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). 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 2 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)	18 Apr 2021 07:56:26 18 Apr 2021 07:56:19
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:24
Signature has been broken.	(b) (4) Teresa Deese (b) (4)	12 Apr 2021 13:49:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Teresa Deese (b) (4)	12 Apr 2021 13:49:09
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:18:58
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 16:15:12

US3202395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:52

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'USA-US128-2021-mRNA-1273-P301000018'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:07:32

US3202395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:52

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea exertional, LLT: Dyspnea exertional - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 21:07:33
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 21:07:33
	(b) (4)	
Data point term sent to Coder System	System	19 Apr 2021 21:06:37
User entered 'DYSPNEA ON EXERTION'	Erica Osmundsen (b) (4)	19 Apr 2021 21:06:18
	(b) (4)	
	(b) (4)	

US3202395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	19 Apr 2021 21:06:18

US3202395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	19 Apr 2021 21:06:18

US3202395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	19 Apr 2021 21:06:18
	(b) (4)	
	(b) (4)	

US3202395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered '06 Apr 2021'	Erica Osmundsen (b) (4)	19 Apr 2021 21:06:18

US3202395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:52

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	19 Apr 2021 21:06:18
	(b) (4)	
	(b) (4)	

US3202395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 21:06:18

US3202395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	19 Apr 2021 21:06:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	19 Apr 2021 21:06:18
	(b) (4)	
	(b) (4)	

US3202395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:52

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	19 Apr 2021 21:06:18
	(b) (4)	
	(b) (4)	

US3202395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 21:06:18

US3202395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:52

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Erica Osmundsen (b) (4)	19 Apr 2021 21:06:18
	(b) (4)	
	(b) (4)	

US3202395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	19 Apr 2021 21:06:18

US3202395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:52

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered '0'	Erica Osmundsen (b) (4)	19 Apr 2021 21:06:18
	(b) (4)	
	(b) (4)	

US3202395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered '0'	Erica Osmundsen (b) (4)	19 Apr 2021 21:06:18

US3202395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered '1'	Erica Osmundsen (b) (4)	19 Apr 2021 21:06:18

US3202395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered '8 Apr 2021'	Erica Osmundsen (b) (4)	19 Apr 2021 21:06:18
	(b) (4)	
	(b) (4)	

US3202395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:52

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered '9 Apr 2021'	Erica Osmundsen (b) (4)	19 Apr 2021 21:06:18

US3202395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:52

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	19 Apr 2021 21:06:18
	(b) (4)	
	(b) (4)	

US3202395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	19 Apr 2021 21:06:18
	(b) (4)	
	(b) (4)	

US3202395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered '0'	Erica Osmundsen (b) (4)	19 Apr 2021 21:06:18
	(b) (4)	
	(b) (4)	

US3202395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered '0'	Erica Osmundsen (b) (4)	19 Apr 2021 21:06:18
	(b) (4)	
	(b) (4)	

US3202395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered '0'	Erica Osmundsen (b) (4)	19 Apr 2021 21:06:18
	(b) (4)	
	(b) (4)	

US3202395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	19 Apr 2021 21:06:18

US3202395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'Not Related (NOT RELATED)'	(b) (4) Erica Osmundsen (b) (4)	19 Apr 2021 21:06:18

US3202395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:52

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Erica Osmundsen (b) (4)	19 Apr 2021 21:06:18
	(b) (4)	
	(b) (4)	

US3202395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:52

None

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered '1'	Erica Osmundsen (b) (4)	19 Apr 2021 21:06:18
	(b) (4)	
	(b) (4)	

US3202395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered '0'	Erica Osmundsen (b) (4)	19 Apr 2021 21:06:18
	(b) (4)	
	(b) (4)	

US3202395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered '0'	Erica Osmundsen (b) (4)	19 Apr 2021 21:06:18
	(b) (4)	
	(b) (4)	

US3202395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:52

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Erica Osmundsen (b) (4)	19 Apr 2021 21:06:18

US3202395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:52

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 18:04:06
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	19 Apr 2021 21:06:18
	(b) (4)	
	(b) (4)	

US3202395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:52

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'SUBJECT PRESENTED AT THE ER ON 08APR2021 REPORTING 2 DAYS OF DYSPNEA ON EXERTION AND HAD JUST HAD AN EPISODE OF WEAKNESS AND HEAVINESS IN CHEST WITH DYSPNEA ON 08APR21, WHICH PROMPTED THE ER VISIT. SHE WAS KEPT OVERNIGHT FOR EVALUATION PER CARDIAC PROTOCOL BUT NO CARDIAC FINDINGS--CATHETERIZATION NEGATIVE FOR BLOCKAGE, BIOMARKER LABS NORMAL, EKG NORMAL. SHE DID HAVE LOW POTASSIUM AND MAGNESIUM NOTED IN CHART, DISCHARGED WITH NON-CARDIAC CHEST PAIN AND WILL F/UP WITH PCP AND CARDIOLOGY'	Erica Osmundsen (b) (4)	19 Apr 2021 21:06:18

US3202395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:52

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 21:06:18

US3202395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:52

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 21:06:18

US3202395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:52

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Apr 2021 21:06:18

US3202395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:52

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:39

US3202395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:52

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:39
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
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)	20 Apr 2021 15:54:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	20 Apr 2021 15:54:38
Data point term sent to Coder	System	20 Apr 2021 15:53:41
User entered 'HEADACHE'	Erica Osmundsen (b) (4)	20 Apr 2021 15:52:55

US3202395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:39
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:52:55

US3202395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:39
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:52:55

US3202395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:39
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:52:55

US3202395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:39
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '13 Oct 2020'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:52:55

US3202395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:52

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:39
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:52:55

US3202395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:39
User entered empty.	System	20 Apr 2021 15:52:55

US3202395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:39
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:52:55

US3202395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:39
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '15 Oct 2020'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:52:55

US3202395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:52

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:39
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:52:55

US3202395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:39
User entered empty.	System	20 Apr 2021 15:52:55

US3202395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:52

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:39
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:52:55

US3202395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:39
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:52:55

US3202395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:52

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:39
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:52:55

US3202395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:52

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:39
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:52:55

US3202395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:39
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:52:55

US3202395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:39
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:52:55

US3202395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:52

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:39
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:52:55

US3202395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:52

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:39
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:52:55

US3202395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:39
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:52:55

US3202395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:39
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:52:55

US3202395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:39
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:52:55

US3202395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:52

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:39
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:52:55

US3202395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:39
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'Related (RELATED)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:52:55

US3202395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:39
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'Not Related (NOT RELATED)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:52:55

US3202395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:52

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:39
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:52:55

US3202395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:52

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:39
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '1'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:52:55

US3202395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:39
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:52:55

US3202395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:39
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:52:55

US3202395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:52

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:39
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:52:55

US3202395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:52

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 20:57:39
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:52:55

US3202395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:52

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:39
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:52:55

US3202395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:52

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:39
User entered '0'	System	20 Apr 2021 15:52:55

US3202395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:52

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:39
User entered '0'	System	20 Apr 2021 15:52:55

US3202395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:52

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:39

US3202395

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:52

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:41

US3202395

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:52

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:41
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
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)	20 Apr 2021 15:57:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 15:57:34
Data point term sent to Coder	System	20 Apr 2021 15:56:43
User entered 'FATIGUE'	Erica Osmundsen (b) (4)	20 Apr 2021 15:56:28

US3202395

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:41
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:56:28

US3202395

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:41
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:56:28

US3202395

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:41
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:56:28

US3202395

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:41
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '12 Oct 2020'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:56:28

US3202395

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:52

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:41
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:56:28

US3202395

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:41
User entered empty.	System	20 Apr 2021 15:56:28

US3202395

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:41
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:56:28

US3202395

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:41
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '16 Oct 2020'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:56:28

US3202395

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:52

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:41
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:56:28

US3202395

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:41
User entered empty.	System	20 Apr 2021 15:56:28

US3202395

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:52

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:41
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:56:28

US3202395

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:41
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:56:28

US3202395

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:52

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:41
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:56:28

US3202395

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:52

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:41
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:56:28

US3202395

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:41
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:56:28

US3202395

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:41
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:56:28

US3202395

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:52

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:41
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:56:28

US3202395

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:52

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:41
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:56:28

US3202395

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:41
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:56:28

US3202395

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:41
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:56:28

US3202395

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:41
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:56:28

US3202395

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:52

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:41
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:56:28

US3202395

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:41
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'Related (RELATED)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:56:28

US3202395

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:41
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'Not Related (NOT RELATED)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:56:28

US3202395

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:52

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:41
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:56:28

US3202395

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:52

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:41
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '1'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:56:28

US3202395

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:41
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:56:28

US3202395

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:41
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:56:28

US3202395

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:52

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:41
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:56:28

US3202395

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:52

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 20:57:41
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:56:28

US3202395

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:52

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:41
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 15:56:28

US3202395

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:52

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:41
User entered '0'	System	20 Apr 2021 15:56:28

US3202395

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:52

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:41
User entered '0'	System	20 Apr 2021 15:56:28

US3202395

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:52

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:41

US3202395

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:52

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:31

US3202395

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:52

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:31
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User coded data point as SOC: Metabolism and nutrition disorders, HLT: Electrolyte and fluid balance conditions, HLT: Electrolyte imbalance NEC, PT: Electrolyte imbalance, LLT: Electrolyte abnormality - version MedDRA\23.0.	Coder Import (b) (4)	20 Apr 2021 21:43:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	20 Apr 2021 21:43:39
Data point term sent to Coder	System	20 Apr 2021 17:43:44
User entered 'ELECTROLYTE ABNORMALITIES'	Erica Osmundsen (b) (4)	20 Apr 2021 17:43:05

US3202395

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:31
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:43:05

US3202395

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:31
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:43:05

US3202395

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:31
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:43:05

US3202395

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:31
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User closed query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	(b) (4)	20 Apr 2021 17:43:42
User closed query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	20 Apr 2021 17:43:42
User entered '08 Apr 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	20 Apr 2021 17:43:42
User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	20 Apr 2021 17:43:05
User opened query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	20 Apr 2021 17:43:05
User entered '08 Apr 2020'	Erica Osmundsen (b) (4)	20 Apr 2021 17:43:05

US3202395

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:52

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:31
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:43:05

US3202395

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:31
User entered empty.	System	20 Apr 2021 17:43:05

US3202395

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:31
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:43:05

US3202395

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:31
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User closed query 'End date is prior to Start date. Please correct.' (Site from System).	(b) (4)	20 Apr 2021 17:43:47
User entered '09 Apr 2021' reason for change: Data Entry Error	System	20 Apr 2021 17:43:47
User opened query 'End date is prior to Start date. Please correct.' (Site from System).	Erica Osmundsen (b) (4)	20 Apr 2021 17:43:42
User entered '09 Apr 2020'	System	20 Apr 2021 17:43:05

US3202395

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:52

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:31
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:43:05

US3202395

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:31
User entered empty.	System	20 Apr 2021 17:43:05

US3202395

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:52

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:31
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:43:05

US3202395

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:31
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:43:05

US3202395

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:52

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:31
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:43:05

US3202395

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:52

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:31
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:43:05

US3202395

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:31
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:43:05

US3202395

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:31
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:43:05

US3202395

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:52

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:31
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:43:05

US3202395

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:52

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:31
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:43:05

US3202395

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:31
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:43:05

US3202395

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:31
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:43:05

US3202395

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:31
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:43:05

US3202395

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:52

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:31
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:43:05

US3202395

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:31
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'Not Related (NOT RELATED)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:43:05

US3202395

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:31
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'Not Related (NOT RELATED)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:43:05

US3202395

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:52

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:31
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:43:05

US3202395

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:52

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:31
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:43:05

US3202395

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:31
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '1'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:43:05

US3202395

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:31
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:43:05

US3202395

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:52

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:31
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:43:05

US3202395

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:52

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 20:57:31
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:43:05

US3202395

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:52

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:31
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 18:04:06
User entered 'SUBJECT PRESENTED AT ER FOR DYSPNEA ON EXERTION AND WAS FOUND TO HAVE LOW POTASSIUM AND MAGNESIUM ON ADMISSION LABS--PLACED ON ELECTROLYTE REPLACEMENT PROTOCOL AND LEVELS WERE NO LONGER LOW UPON REPEAT LABS PRIOR TO DISCHARGE THE FOLLOWING DAY. THESE WERE NOT THE REASON FOR HOSPITALIZATION NOR WERE THEY SEVERELY DEFICIENT.'	Erica Osmundsen (b) (4)	20 Apr 2021 17:43:05

US3202395

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:52

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:31
User entered '0'	System	20 Apr 2021 17:43:05

US3202395

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:52

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:31
User entered '1'	System	20 Apr 2021 17:43:05

US3202395

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:52

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:31

US3202395

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:52

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:32

US3202395

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:52

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Non-cardiac chest pain, LLT: Non-cardiac chest pain - version MedDRA\23.0.	Coder Import (b) (4)	20 Apr 2021 21:54:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	20 Apr 2021 21:54:48
Data point term sent to Coder	System	20 Apr 2021 17:48:01
User entered 'NON-CARDIAC CHEST PAIN OF UNKNOWN ETIOLOGY'	Erica Osmundsen (b) (4)	20 Apr 2021 17:47:19

US3202395

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:47:19

US3202395

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:47:19

US3202395

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:47:19

US3202395

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '08 Apr 2021'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:47:19

US3202395

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:52

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:47:19

US3202395

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:32
User entered empty.	System	20 Apr 2021 17:47:19

US3202395

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:47:19

US3202395

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '08 Apr 2021'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:47:19

US3202395

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:52

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:47:19

US3202395

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:32
User entered empty.	System	20 Apr 2021 17:47:19

US3202395

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:52

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:47:19

US3202395

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:47:19

US3202395

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:52

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:47:19

US3202395

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:52

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:47:19

US3202395

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:47:19

US3202395

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:47:19

US3202395

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:52

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:47:19

US3202395

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:52

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:47:19

US3202395

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:47:19

US3202395

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:47:19

US3202395

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:47:19

US3202395

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:52

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:47:19

US3202395

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Apr 2021 17:49:00
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	20 Apr 2021 17:49:00
User opened query 'Data is required. Please complete.' (Site from System).	Erica Osmundsen (b) (4)	20 Apr 2021 17:49:00
User entered empty.	System	20 Apr 2021 17:47:19
	Erica Osmundsen (b) (4)	20 Apr 2021 17:47:19

US3202395

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'Not Related (NOT RELATED)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:47:19

US3202395

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:52

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:47:19

US3202395

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:52

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '1'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:47:19

US3202395

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:47:19

US3202395

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:47:19

US3202395

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:52

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	20 Apr 2021 17:49:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Apr 2021 17:49:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	20 Apr 2021 17:49:00
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Apr 2021 17:47:19
User entered empty.	Erica Osmundsen (b) (4)	20 Apr 2021 17:47:19

US3202395

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:52

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 20:57:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:47:19

US3202395

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:52

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:32
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 18:04:06
User entered 'SUBJECT PRESENTED AT ER FOR PERSISTENT DYSPNEA UPON EXERTION AND ONE EPISODE OF CHEST PAIN. SHE WAS ADMITTED OVERNIGHT FOR EVALUATION AND CARDIAC WORKUP BUT ALL CARDIAC TESTS WERE NEGATIVE (NORMAL ECG, NO STENOSIS FOUND ON CATHETERIZATION, CARDIAC BIOMARKER LABS ALL NORMAL). NITROGLYCERIN WAS ORDERED AS PRN, BUT WAS NOT USED SO NO TREATMENT NOTED FOR THIS AE AS OF THIS TIME.'	Erica Osmundsen (b) (4)	20 Apr 2021 17:47:19

US3202395

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:52

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:32
User entered '0'	System	20 Apr 2021 17:47:19

US3202395

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:52

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:32
User entered '1'	System	20 Apr 2021 17:47:19

US3202395

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:52

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:57:32

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:41:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:31:32
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User closed query 'Per CDM: Per previous query response "Updated"; however, the update is not obvious please provide location of update such as log line number. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:29:17
Query 'Per CDM: Per previous query response "Updated"; however, the update is not obvious please provide location of update such as log line number. Thank you. ' answered with 'See Tylenol entry in ECRF' (Site from DM).	zackery harmon (b) (4) (b) (4)	25 Jan 2021 21:45:56
User opened query 'Per CDM: Per previous query response "Updated"; however, the update is not obvious please provide location of update such as log line number. Thank you. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 13:51:58
User closed query 'Per DM CLR: Per Diary Dose 2 Day 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)	25 Jan 2021 13:51:58
Query 'Per DM CLR: Per Diary Dose 2 Day 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)	21 Jan 2021 13:25:32

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:41:52

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Per Diary Dose 2 Day 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 11:25:43
User closed query 'Per CDM: Were any prior/concomitant medications and/or vaccinations taken? Is recorded as "YES" however, prior/concomitant medications and/or vaccinations taken form has not been completed? Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 15:25:24
Query 'Per CDM: Were any prior/concomitant medications and/or vaccinations taken? Is recorded as "YES" however, prior/concomitant medications and/or vaccinations taken form has not been completed? Please update accordingly.' answered with 'QUERY CORRECTED' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 18:46:38
User opened query 'Per CDM: Were any prior/concomitant medications and/or vaccinations taken? Is recorded as "YES" however, prior/concomitant medications and/or vaccinations taken form has not been completed? Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 09:01:09
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	12 Sep 2020 16:15:39

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Oct 2020 18:09:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 18:09:49
Data point term sent to Coder	System	02 Oct 2020 18:08:30
User entered 'SIMVASTATIN'	(b) (4), (b) (6)	02 Oct 2020 18:07:42

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:07:42

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'HYPERCHOLESTEROLEMIA'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:07:42

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '10'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:07:42

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:07:42

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:07:42

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:07:42

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:07:42

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:07:42

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:07:42

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'UN UNK 2004'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:07:42

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:52

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:07:42

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:07:42

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:07:42

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:07:42

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 18:07:42

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 18:07:42

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 18:07:42

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	03 Oct 2020 04:24:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 04:24:47
Data point term sent to Coder	System	02 Oct 2020 18:10:34
User entered 'TRAMADOL'	(b) (4), (b) (6)	02 Oct 2020 18:09:43

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:09:43

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'SCIATIC NERVE PAIN'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:09:43

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '50'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:09:43

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:09:43

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:09:43

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'three times daily (TID)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:09:43

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:09:43

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:09:43

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:09:43

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'UN UNK 2008'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:09:43

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:52

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:09:43

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:09:43

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:09:43

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:09:43

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	02 Oct 2020 18:09:43

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 18:09:43

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 18:09:43

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: DIURETICS AND POTASSIUM-SPARING AGENTS IN COMBINATION, ATC: LOW-CEILING DIURETICS AND POTASSIUM-SPARING AGENTS, PRODUCT: HYDROCHLOROTHIAZIDE;TRIAMTERENE, PRODUCTSYNONYM: TRIAMTERENE HCTZ - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Oct 2020 18:13:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 18:13:50
Data point term sent to Coder	System	02 Oct 2020 18:12:36
User entered 'TRIAMTERENE HCTZ'	(b) (4), (b) (6)	02 Oct 2020 18:11:58

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:11:58

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User closed query 'Per CDM: Re-query: Response provided as 'corrected' However data has not been updated yet. this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:01:49
Query 'Per CDM: Re-query: Response provided as 'corrected' However data has not been updated yet. this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 22:08:49
User opened query 'Per CDM: Re-query: Response provided as 'corrected' However data has not been updated yet. this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 15:57:32
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 15:57:32
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 21:25:14
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 12:09:53
User entered 'HYPERTENSION'	(b) (4), (b) (6)	02 Oct 2020 18:11:58

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User closed query 'Per DM CLR: Note, that 375/25mg recorded in Dose/Dose Unit fields is not an available dosage strength option for this medication. Please review and correct the dose recorded as appropriate. Otherwise, provide explanation for alternate dosage.' (Site from DM). Query 'Per DM CLR: Note, that 375/25mg recorded in Dose/Dose Unit fields is not an available dosage strength option for this medication. Please review and correct the dose recorded as appropriate. Otherwise, provide explanation for alternate dosage.' answered with 'VERIFIED WITH SUBJECT DOSAGE IS 37.5/25 MG' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:58:10
User entered '37.5/25' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 21:23:29
User opened query 'Per DM CLR: Note, that 375/25mg recorded in Dose/Dose Unit fields is not an available dosage strength option for this medication. Please review and correct the dose recorded as appropriate. Otherwise, provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 12:09:59
User entered '375/25'	(b) (4), (b) (6)	02 Oct 2020 18:11:58

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:11:58

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:11:58

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:11:58

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:11:58

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:11:58

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:11:58

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'UN UNK 2008'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:11:58

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:52

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:11:58

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:11:58

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:11:58

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:11:58

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 18:11:58

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 18:11:58

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 18:11:58

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	02 Oct 2020 18:14:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 18:14:50
Data point term sent to Coder	System	02 Oct 2020 18:13:38
User entered 'LEVOTHYROXINE'	(b) (4), (b) (6)	02 Oct 2020 18:13:05

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:13:05

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'HYPOTHYROIDISM'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:13:05

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '88'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:13:05

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:13:05

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:13:05

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:13:05

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:13:05

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:13:05

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:13:05

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'UN UNK 1993'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:13:05

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:52

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:13:05

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:13:05

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:13:05

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:13:05

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 18:13:05

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 18:13:05

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 18:13:05

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:52

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	02 Oct 2020 18:15:50
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	02 Oct 2020 18:15:50
	(b) (4)	
Data point term sent to Coder	System	02 Oct 2020 18:14:39
User entered 'GABAPENTIN'	(b) (4), (b) (6)	02 Oct 2020 18:14:21

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:14:21

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'SCIATIC NERVE PAIN'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:14:21

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '100'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:14:21

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:14:21

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:14:21

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:14:21

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:14:21

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:14:21

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:14:21

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'UN Mar 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:14:21

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:52

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:14:21

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:14:21

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:14:21

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:14:21

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	02 Oct 2020 18:14:21

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 18:14:21

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 18:14:21

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	02 Oct 2020 18:17:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 18:17:44
Data point term sent to Coder	System	02 Oct 2020 18:16:41
User entered 'FISH OIL'	(b) (4), (b) (6)	02 Oct 2020 18:16:04

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User closed query 'Per DM CLR: This medication was given as SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 09:39:21
Query 'Per DM CLR: This medication was given as SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable.' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 21:20:43
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 21:20:25
User opened query 'Per DM CLR: This medication was given as SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 09:45:12
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 18:16:04

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'SUPPLEMENT'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:16:04

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:47:45
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'VERIFIED AND CORRECTED' (Site from DM).	(b) (4), (b) (6)	24 Jan 2021 18:03:57
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 02:37:50
User entered '4' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 21:20:25
User entered '1'	(b) (4), (b) (6)	02 Oct 2020 18:16:04

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'g (g)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	24 Jan 2021 18:03:35
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 21:20:25
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	02 Oct 2020 18:16:04

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 09:39:28
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 21:20:35
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 09:45:23
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 18:16:04

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:16:04

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:16:04

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:16:04

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:16:04

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:16:04

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:52

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:16:04

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:16:04

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:16:04

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:16:04

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 18:16:04

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 18:16:04

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 18:16:04

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	02 Oct 2020 18:18:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 18:18:48
Data point term sent to Coder	System	02 Oct 2020 18:17:43
User entered 'VITAMIN B12'	(b) (4), (b) (6)	02 Oct 2020 18:16:56

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User closed query 'Per DM CLR: This medication was given as SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 09:39:45
Query 'Per DM CLR: This medication was given as SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable.' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 18:51:38
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 18:51:19
User opened query 'Per DM CLR: This medication was given as SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 09:48:52
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 18:16:56

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'SUPPLEMENT'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:16:56

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '1'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:16:56

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 09:39:48
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 20:22:45
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 20:22:22
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 09:48:47
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	02 Oct 2020 18:16:56

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:16:56

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:16:56

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:16:56

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:16:56

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:16:56

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:16:56

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:52

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:16:56

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:16:56

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:16:56

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:16:56

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 18:16:56

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 18:16:56

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 18:16:56

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: VASOPROTECTIVES, ATC: CAPILLARY STABILIZING AGENTS, ATC: BIOFLAVONOIDS, PRODUCT: BIOFLAVONOIDS NOS, PRODUCTSYNONYM: BIOFLAVONOIDS [BIOFLAVONOIDS NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Oct 2020 12:18:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 12:18:21
Data point term sent to Coder	System	02 Oct 2020 18:18:48
User entered 'CITRUS BIOFLAVONOIDS'	(b) (4), (b) (6)	02 Oct 2020 18:18:47

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User closed query 'Per DM CLR: This medication was given as SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 09:40:05
Query 'Per DM CLR: This medication was given as SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable.' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 19:07:27
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 18:53:56
User opened query 'Per DM CLR: This medication was given as SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 09:45:54
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 18:18:47

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'SUPPLEMENT'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:18:47

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '250' reason for change: Data Entry	(b) (4)	17 Dec 2020 18:53:56
Error	(b) (4), (b) (6)	
User entered '1'	(b) (4), (b) (6)	02 Oct 2020 18:18:47

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 09:40:08
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 19:07:41
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 18:53:56
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 09:45:42
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	02 Oct 2020 18:18:47

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:18:47

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:18:47

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:18:47

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:18:47

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:18:47

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:18:47

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:52

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:18:47

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:18:47

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:18:47

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:18:47

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 18:18:47

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 18:18:47

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 18:18:47

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: NICOTINAMIDE, PRODUCTSYNONYM: NIACINAMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	02 Oct 2020 18:21:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 18:21:57
Data point term sent to Coder	System	02 Oct 2020 18:20:57
User entered 'NIACINAMIDE'	(b) (4), (b) (6)	02 Oct 2020 18:20:46

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User closed query 'Per DM CLR: This medication was given as SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 09:40:42
Query 'Per DM CLR: This medication was given as SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable.' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 19:18:33
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 19:17:01
User opened query 'Per DM CLR: This medication was given as SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 09:49:27
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 18:20:46

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'SUPPLEMENT'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:20:46

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '1'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:20:46

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 09:40:44
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 19:18:40
User entered 'g (g)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 19:17:01
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 09:49:34
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	02 Oct 2020 18:20:46

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:20:46

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:20:46

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:20:46

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:20:46

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:20:46

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:20:46

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:52

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:20:46

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:20:46

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:20:46

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:20:46

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 18:20:46

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 18:20:46

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 18:20:46

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: UBIDECARENONE, PRODUCTSYNONYM: COQ10 [UBIDECARENONE] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	02 Oct 2020 18:22:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 18:22:46
Data point term sent to Coder	System	02 Oct 2020 18:22:01
User entered 'CoQ10'	(b) (4), (b) (6)	02 Oct 2020 18:21:36

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User closed query 'Per DM CLR: This medication was given as SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 09:40:59
Query 'Per DM CLR: This medication was given as SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable.' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 20:28:06
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 20:27:54
User opened query 'Per DM CLR: This medication was given as SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 09:46:39
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 18:21:36

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'SUPPLEMENT'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:21:36

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '100' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:27:54
User entered '1'	(b) (4), (b) (6)	02 Oct 2020 18:21:36

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 09:41:02
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 20:28:16
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 20:27:54
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 09:46:48
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	02 Oct 2020 18:21:36

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:21:36

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:21:36

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:21:36

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:21:36

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:21:36

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:21:36

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:21:36

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:21:36

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:21:36

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:21:36

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 18:21:36

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 18:21:36

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 18:21:36

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:52

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: SILYBUM MARIANUM, PRODUCTSYNONYM: MILK THISTLE [SILYBUM MARIANUM] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	02 Nov 2020 13:47:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Nov 2020 13:47:20
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: SILYBUM MARIANUM HERB - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 18:28:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 18:28:46
Data point term sent to Coder	System	02 Oct 2020 18:27:10
User entered 'MILK THISTLE'	(b) (4), (b) (6)	02 Oct 2020 18:26:44

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User closed query 'Per DM CLR: This medication was given as SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 09:41:12
Query 'Per DM CLR: This medication was given as SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable.' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 20:40:12
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 20:40:02
User opened query 'Per DM CLR: This medication was given as SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 09:50:29
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 18:26:44

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'SUPPLEMENT'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:26:44

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '175' reason for change: Data Entry	(b) (4)	17 Dec 2020 20:40:02
Error	(b) (4), (b) (6)	
User entered '1'	(b) (4), (b) (6)	02 Oct 2020 18:26:44

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 09:41:14
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 20:40:28
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 20:40:02
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 09:50:37
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	02 Oct 2020 18:26:44

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:26:44

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:26:44

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:26:44

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:26:44

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:26:44

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'UN Mar 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:26:44

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:52

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:26:44

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:26:44

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:26:44

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:26:44

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 18:26:44

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 18:26:44

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 18:26:44

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: CURCUMA LONGA, PRODUCTSYNONYM: TURMERIC [CURCUMA LONGA] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	02 Oct 2020 18:28:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 18:28:47
Data point term sent to Coder	System	02 Oct 2020 18:28:11
User entered 'TUMERIC'	(b) (4), (b) (6)	02 Oct 2020 18:27:35

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User closed query 'Per DM CLR: This medication was given as SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 09:41:33
Query 'Per DM CLR: This medication was given as SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable. ' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 20:41:58
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 20:40:44
User opened query 'Per DM CLR: This medication was given as SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable. ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 09:51:24
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 18:27:35

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'SUPPLEMENT'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:27:35

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '700' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:41:36
User entered '1'	(b) (4), (b) (6)	02 Oct 2020 18:27:35

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 09:41:34
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 20:42:11
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 20:41:36
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 09:51:32
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	02 Oct 2020 18:27:35

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:27:35

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:27:35

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:27:35

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:27:35

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:27:35

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:27:35

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:52

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:27:35

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:27:35

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:27:35

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:27:35

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 18:27:35

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 18:27:35

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 18:27:35

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:52

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: GINKGO BILOBA, PRODUCTSYNONYM: GINKO BILOBA [GINKGO BILOBA] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	02 Oct 2020 18:30:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 18:30:53
Data point term sent to Coder	System	02 Oct 2020 18:30:16
User entered 'GINKO BILOBA'	(b) (4), (b) (6)	02 Oct 2020 18:29:36

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User closed query 'Per DM CLR: This medication was given as SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 09:42:07
Query 'Per DM CLR: This medication was given as SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable.' answered with 'CIRRECTED ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 20:45:59
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 20:45:30
User opened query 'Per DM CLR: This medication was given as SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 09:52:04
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 18:29:36

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'SUPPLEMENT'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:29:36

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '80' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:45:30
User entered '1'	(b) (4), (b) (6)	02 Oct 2020 18:29:36

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 09:42:09
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 20:46:08
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 20:45:30
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 09:52:09
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	02 Oct 2020 18:29:36

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:29:36

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:29:36

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:29:36

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:29:36

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:29:36

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:29:36

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:52

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:29:36

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:29:51
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 18:29:36

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User closed query 'Ongoing is No, however End date System is missing. Please provide.' (Site from System).		02 Oct 2020 18:29:51
User opened query 'Ongoing is No, however End date System is missing. Please provide.' (Site from System).		02 Oct 2020 18:29:36
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 18:29:36

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:29:36

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 18:29:36

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 18:29:36

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 18:29:36

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:41:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM CITRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 18:32:57
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 18:32:57
	(b) (4)	
Data point term sent to Coder	System	02 Oct 2020 18:32:21
User entered 'MAGNESIUM CITRATE'	(b) (4), (b) (6)	02 Oct 2020 18:32:05

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:41:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User closed query 'Per DM CLR: This medication was given as SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 09:42:22
Query 'Per DM CLR: This medication was given as SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable.' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 20:50:09
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 20:49:57
User opened query 'Per DM CLR: This medication was given as SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 09:54:49
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 18:32:05

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:41:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'SUPPLEMENT'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:32:05

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:41:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '420' reason for change: Data Entry	(b) (4)	17 Dec 2020 20:49:57
Error	(b) (4), (b) (6)	
User entered '1'	(b) (4), (b) (6)	02 Oct 2020 18:32:05

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:41:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 09:42:24
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 20:50:19
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 20:49:57
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 09:54:42
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	02 Oct 2020 18:32:05

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:41:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:32:05

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:41:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:32:05

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:41:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:32:05

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:41:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:32:05

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:41:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:32:05

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:41:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:32:05

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:41:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:32:05

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:41:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:32:05

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:41:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:32:05

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:41:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:32:05

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:41:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 18:32:05

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 18:32:05

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 18:32:05

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:41:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER VITAMIN PRODUCTS, COMBINATIONS, ATC: COMBINATIONS OF VITAMINS, PRODUCT: COLECALCIFEROL;MENAQUINONE-7, PRODUCTSYNONYM: VITAMIN D3 K2 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	03 Oct 2020 04:18:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 04:18:51
Data point term sent to Coder	System	02 Oct 2020 18:36:28
User entered 'VITAMIN D3 & K2'	(b) (4), (b) (6)	02 Oct 2020 18:35:49

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:41:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User closed query 'Per DM CLR: This medication was given as SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 09:42:48
Query 'Per DM CLR: This medication was given as SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable.' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 21:03:42
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 21:03:25
User opened query 'Per DM CLR: This medication was given as SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 09:55:31
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 18:35:49

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:41:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'SUPPLEMENT'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:35:49

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:41:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User closed query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than a number of tablets. Please verify the dose and unit, and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 09:42:50
Query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than a number of tablets. Please verify the dose and unit, and update as appropriate. ' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 21:03:50
User entered '800' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 21:03:25
User opened query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than a number of tablets. Please verify the dose and unit, and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 09:56:12
User entered '1'	(b) (4), (b) (6)	02 Oct 2020 18:35:49

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:41:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'IU (IU)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	17 Dec 2020 21:03:25
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	02 Oct 2020 18:35:49

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:41:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:35:49

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:41:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:35:49

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:41:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:35:49

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:41:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:35:49

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:41:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:35:49

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:41:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:35:49

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:41:52

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:35:49

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:41:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:35:49

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:41:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:35:49

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:41:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:35:49

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:41:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 18:35:49

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 18:35:49

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 18:35:49

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:41:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, PRODUCT: DL-ALPHA TOCOPHERYL ACETATE;RETINOL PALMITATE;XANTOFYL;ZEAXANTHIN;ZINC OXIDE, PRODUCTSYNONYM: LUTEIN PLUS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Oct 2020 09:20:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 09:20:21
Data point term sent to Coder	System	02 Oct 2020 18:37:29
User entered 'BIOTEN PLUS LUTEIN'	(b) (4), (b) (6)	02 Oct 2020 18:37:00

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:41:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User closed query 'Per DM CLR: This medication was given as SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 09:43:01
Query 'Per DM CLR: This medication was given as SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable.' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 21:06:51
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 21:06:41
User opened query 'Per DM CLR: This medication was given as SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 09:47:25
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 18:37:00

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:41:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'SUPPLEMENT'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:37:00

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:41:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '5' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	17 Dec 2020 21:06:41
User entered '1'	(b) (4), (b) (6)	02 Oct 2020 18:37:00

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:41:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 09:43:03
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 21:08:32
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 21:06:41
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 09:47:14
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	02 Oct 2020 18:37:00

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:41:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:37:00

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:41:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:37:00

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:41:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:37:00

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:41:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:37:00

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:41:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:37:00

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:41:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:37:00

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:41:52

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:37:00

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:41:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:37:00

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:41:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:37:00

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:41:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:37:00

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:41:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 18:37:00

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 18:37:00

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 18:37:00

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:41:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: GLUCOSAMINE SULFATE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Oct 2020 18:42:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 18:42:48
Data point term sent to Coder	System	02 Oct 2020 18:41:38
User entered 'GLUCOSAMINE SULFATE'	(b) (4), (b) (6)	02 Oct 2020 18:40:44

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:41:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User closed query 'Per DM CLR: This medication was given as SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 09:43:23
Query 'Per DM CLR: This medication was given as SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable.' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 21:11:58
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 21:11:46
User opened query 'Per DM CLR: This medication was given as SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 09:56:49
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 18:40:44

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:41:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'SUPPLEMENT'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:40:44

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:41:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '750' reason for change: Data Entry	(b) (4)	17 Dec 2020 21:11:46
Error	(b) (4), (b) (6)	
User entered '1'	(b) (4), (b) (6)	02 Oct 2020 18:40:44

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:41:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 09:43:25
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 21:12:06
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 21:11:46
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 09:56:58
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	02 Oct 2020 18:40:44

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:41:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:40:44

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:41:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:40:44

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:41:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:40:44

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:41:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:40:44

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:41:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:40:44

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:41:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:40:44

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:41:52

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:40:44

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:41:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:40:44

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:41:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:40:44

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:41:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:40:44

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:41:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 18:40:44

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 18:40:44

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 18:40:44

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:41:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: BILE AND LIVER THERAPY, ATC: LIVER THERAPY, LIPOTROPICS, ATC: LIVER THERAPY, PRODUCT: CHOLINE BITARTRATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	02 Oct 2020 19:45:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 19:45:53
Data point term sent to Coder	System	02 Oct 2020 18:42:39
User entered 'CHOLINE BITARTRATE'	(b) (4), (b) (6)	02 Oct 2020 18:42:23

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:41:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User closed query 'Per DM CLR: This medication was given as SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 09:43:45
Query 'Per DM CLR: This medication was given as SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable.' answered with 'CORRECTED ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 21:13:45
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 21:13:35
User opened query 'Per DM CLR: This medication was given as SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 09:47:47
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 18:42:23

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:41:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'SUPPLEMENT'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:42:23

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:41:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '250' reason for change: Data Entry	(b) (4)	17 Dec 2020 21:13:35
Error	(b) (4), (b) (6)	
User entered '1'	(b) (4), (b) (6)	02 Oct 2020 18:42:23

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:41:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 09:43:47
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 21:13:59
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 21:13:35
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 09:47:56
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	02 Oct 2020 18:42:23

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:41:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:42:23

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:41:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:42:23

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:41:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:42:23

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:41:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:42:23

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:41:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:42:23

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:41:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:42:23

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:41:52

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:42:23

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:41:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:42:23

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:41:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:42:23

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:41:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:42:23

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:41:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 18:42:23

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 18:42:23

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 18:42:23

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:41:52

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	25 Jan 2021 21:44:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Jan 2021 21:44:53
Data point term sent to Coder Coding entries removed.	System zackery harmon (b) (4)	25 Jan 2021 21:44:13 25 Jan 2021 21:43:52
User closed query 'Per CDM: Please review the Drug spelling and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 12:18:46
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)	04 Nov 2020 18:52:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Nov 2020 18:52:27
Query 'Per CDM: Please review the Drug spelling and update accordingly.' answered with 'QUERY CORRECTED' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 18:51:41
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	04 Nov 2020 18:51:37 04 Nov 2020 18:51:05
User entered 'TYLENOL' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Nov 2020 18:51:05
User opened query 'Per CDM: Please review the Drug spelling and update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 14:30:36
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)	14 Oct 2020 16:51:29

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:41:52

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 16:51:29
Data point term sent to Coder	System	14 Oct 2020 16:29:27
User entered 'Tyleno'	Lilian Nukuna (b) (4) (b) (4)	14 Oct 2020 16:29:10

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:41:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered 'No (N)'	Lilian Nukuna (b) (4)	14 Oct 2020 16:29:10
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:41:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User closed query 'Per CDM: Response does not satisfy query. Please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria else add an entry and applicable details to the AE eCRF as appropriate. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 08:56:28
Query 'Per CDM: Response does not satisfy query. Please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria else add an entry and applicable details to the AE eCRF as appropriate. Thank you' answered with 'this was a diary entry & solicited event box checked. check your guidelines to see if that qualifies for AE' (Site from DM).	Teresa Deese (b) (4)	10 Mar 2021 13:55:54
User opened query 'Per CDM: Response does not satisfy query. Please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria else add an entry and applicable details to the AE eCRF as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 08:39:56
User closed query 'Per DM CLR: Noted addition of HEADACHE as indication. However, there is no AE that matches HEADACHE 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)	10 Mar 2021 08:39:56

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:41:52

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Noted addition of HEADACHE as indication. However, there is no AE that matches HEADACHE 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 'was this a solicited event & is the solicited event box checked?' (Site from DM).	Teresa Deese (b) (4)	09 Mar 2021 19:36:17
User opened query 'Per DM CLR: Noted addition of HEADACHE as indication. However, there is no AE that matches HEADACHE 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)	09 Mar 2021 05:33:20
User entered 'BACK PAIN Diary entry Headache Con Med' reason for change: Data Entry Error	zackery harmon (b) (4)	25 Jan 2021 21:43:52
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 13:49:35

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:41:52

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	24 Jan 2021 18:53:49
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.'	(b) (4), (b) (6)	22 Jan 2021 03:37:33
(Site from DM). User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition #9 SCIATIC NERVE PAIN worsened. If yes, please review if an AE of Worsening MH condition should be recorded, and update con med indication or provide clarification.'	(b) (4), (b) (6)	28 Dec 2020 19:19:53
(Site from DM). Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition #9 SCIATIC NERVE PAIN worsened. If yes, please review if an AE of Worsening MH condition should be recorded, and update con med indication or provide clarification.'	(b) (4), (b) (6)	17 Dec 2020 21:30:46
' answered with 'SUBJECT HAS EXTENSIVE HX OF BACK PAIN. SUPPLEMENTS PRESCRIBED PAIN MEDS WITH OTC MEDS PRN.' (Site from DM).		
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition #9 SCIATIC NERVE PAIN worsened. If yes, please review if an AE of Worsening MH condition should be recorded, and update con med indication or provide clarification.'	(b) (4), (b) (6)	15 Dec 2020 11:29:40
(Site from DM). Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 11:28:45

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:41:52

[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. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 13:14:42
User entered 'back pain'	Lilian Nukuna (b) (4) (b) (4)	14 Oct 2020 16:29:10

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:41:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered '500'	Lilian Nukuna (b) (4)	14 Oct 2020 16:29:10
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:41:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered 'mg (mg)'	Lilian Nukuna (b) (4)	14 Oct 2020 16:29:10
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:41:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered empty.	Lilian Nukuna (b) (4)	14 Oct 2020 16:29:10
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:41:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered 'as needed (PRN)'	Lilian Nukuna (b) (4)	14 Oct 2020 16:29:10
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:41:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered empty.	Lilian Nukuna (b) (4)	14 Oct 2020 16:29:10
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:41:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered 'Oral (ORAL)'	Lilian Nukuna (b) (4)	14 Oct 2020 16:29:10
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:41:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered empty.	Lilian Nukuna (b) (4)	14 Oct 2020 16:29:10
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:41:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered '13 Oct 2020'	Lilian Nukuna (b) (4)	14 Oct 2020 16:29:10
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:41:52

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered '0'	Lilian Nukuna (b) (4)	14 Oct 2020 16:29:10
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:41:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	17 Dec 2020 21:27:36
User entered 'No (N)'	Lilian Nukuna (b) (4) (b) (4)	14 Oct 2020 16:29:10

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:41:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	(b) (4)	17 Dec 2020 21:28:33
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 21:28:33
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	17 Dec 2020 21:27:36
User entered '13 Oct 2020'	Lilian Nukuna (b) (4)	14 Oct 2020 16:29:10
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:41:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of BACK PAIN DIARY ENTRY HEADACHE CON MED in AE eCRF within this timeframe. Review response if this should be updated to "No" as appropriate. Otherwise, update Con Med eCRF or provide comment. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Mar 2021 05:15:42
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of BACK PAIN DIARY ENTRY HEADACHE CON MED in AE eCRF within this timeframe. Review response if this should be updated to "No" as appropriate. Otherwise, update Con Med eCRF or provide comment. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 05:15:06
User entered 'Yes (Y)' reason for change: Data Entry Error	zackery harmon (b) (4)	25 Jan 2021 21:50:11
User entered 'No (N)'	Lilian Nukuna (b) (4)	14 Oct 2020 16:29:10

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:41:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 16:29:10

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 16:29:10

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 16:29:10

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:41:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
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.	(b) (4) Coder Import (b) (4) (b) (4)	19 Oct 2020 16:12:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 16:12:25
Data point term sent to Coder	System	19 Oct 2020 16:11:57
User entered 'ibuprofen'	Lilian Nukuna (b) (4) (b) (4)	19 Oct 2020 16:11:30

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:41:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered 'No (N)'	Lilian Nukuna (b) (4)	19 Oct 2020 16:11:30
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:41:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition #9 SCIATIC NERVE PAIN worsened. If yes, please review if an AE of Worsening MH condition should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Dec 2020 19:20:23
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition #9 SCIATIC NERVE PAIN worsened. If yes, please review if an AE of Worsening MH condition should be recorded, and update con med indication or provide clarification. ' answered with 'SUBJECT HAS EXTENSIVE HX OF BACK PAIN. SUPPLEMENTS PRESCRIBED PAIN MEDS WITH OTC MEDS PRN.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 21:31:16
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition #9 SCIATIC NERVE PAIN worsened. If yes, please review if an AE of Worsening MH condition should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 11:30:17
User entered 'chronic back pain'	Lilian Nukuna (b) (4) (b) (4)	19 Oct 2020 16:11:30

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:41:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered '800'	Lilian Nukuna (b) (4)	19 Oct 2020 16:11:30
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:41:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered 'mg (mg)'	Lilian Nukuna (b) (4)	19 Oct 2020 16:11:30
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:41:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered empty.	Lilian Nukuna (b) (4)	19 Oct 2020 16:11:30
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:41:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered 'as needed (PRN)'	Lilian Nukuna (b) (4)	19 Oct 2020 16:11:30
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:41:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered empty.	Lilian Nukuna (b) (4)	19 Oct 2020 16:11:30
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:41:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
User entered 'Oral (ORAL)'	(b) (4) Lilian Nukuna (b) (4)	19 Oct 2020 16:11:30
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:41:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered empty.	Lilian Nukuna (b) (4)	19 Oct 2020 16:11:30
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:41:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered '15 Oct 2020'	Lilian Nukuna (b) (4)	19 Oct 2020 16:11:30
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:41:52

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered '0'	Lilian Nukuna (b) (4)	19 Oct 2020 16:11:30
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:41:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered 'Yes (Y)'	Lilian Nukuna (b) (4)	19 Oct 2020 16:11:30
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:41:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered empty.	Lilian Nukuna (b) (4)	19 Oct 2020 16:11:30
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:41:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered 'No (N)'	Lilian Nukuna (b) (4)	19 Oct 2020 16:11:30
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:41:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 16:11:30

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 16:11:30

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 16:11:30

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:41:52

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Apr 2021 17:55:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 17:55:30
Data point term sent to Coder User entered 'ASPIRIN'	System Erica Osmundsen (b) (4) (b) (4)	20 Apr 2021 17:55:12 20 Apr 2021 17:54:31

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:41:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	20 Apr 2021 17:54:31
	(b) (4)	
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:41:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered 'CARDIOVASCULAR PROPHYLAXIS'	Erica Osmundsen (b) (4)	20 Apr 2021 17:54:31

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:41:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered '81'	Erica Osmundsen (b) (4)	20 Apr 2021 17:54:31
	(b) (4)	
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:41:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	20 Apr 2021 17:54:31
	(b) (4)	
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:41:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	20 Apr 2021 17:54:31
	(b) (4)	
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:41:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'once daily (QD)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 17:54:31

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:41:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	20 Apr 2021 17:54:31
	(b) (4)	
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:41:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	20 Apr 2021 17:54:31
	(b) (4)	
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:41:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	20 Apr 2021 17:54:31
	(b) (4)	
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:41:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered '09 Apr 2021'	Erica Osmundsen (b) (4)	20 Apr 2021 17:54:31

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:41:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered '0'	Erica Osmundsen (b) (4)	20 Apr 2021 17:54:31

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:41:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	20 Apr 2021 17:54:31

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:41:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	20 Apr 2021 17:54:31
	(b) (4)	
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:41:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	20 Apr 2021 17:54:31
	(b) (4)	
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:41:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 17:54:31

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 17:54:31

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Apr 2021 17:54:31

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:41:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: POTASSIUM - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	21 Apr 2021 08:28:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 08:28:42
Data point term sent to Coder	System	20 Apr 2021 18:08:49
User entered 'potassium supplement'	Erica Osmundsen (b) (4) (b) (4)	20 Apr 2021 18:08:14

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:41:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	20 Apr 2021 18:08:14
	(b) (4)	
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:41:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'electrolyte abnormalities'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 18:08:14

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:41:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered '20'	Erica Osmundsen (b) (4)	20 Apr 2021 18:08:14
	(b) (4)	
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:41:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'Other (OTHER)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 18:08:14

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:41:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered 'mEq/hour'	Erica Osmundsen (b) (4)	20 Apr 2021 18:08:14
	(b) (4)	
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:41:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered 'as needed (PRN)'	Erica Osmundsen (b) (4)	20 Apr 2021 18:08:14
	(b) (4)	
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:41:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	20 Apr 2021 18:08:14
	(b) (4)	
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:41:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 18:08:14

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:41:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	20 Apr 2021 18:08:14
	(b) (4)	
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:41:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered '08 Apr 2021'	Erica Osmundsen (b) (4)	20 Apr 2021 18:08:14

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:41:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered '0'	Erica Osmundsen (b) (4)	20 Apr 2021 18:08:14

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:41:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	20 Apr 2021 18:08:14
	(b) (4)	
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:41:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered '09 Apr 2021'	Erica Osmundsen (b) (4)	20 Apr 2021 18:08:14
	(b) (4)	
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:41:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	20 Apr 2021 18:08:14

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:41:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 18:08:14

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 18:08:14

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 18:08:14

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:41:52

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Apr 2021 21:18:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:18:43
Data point term sent to Coder	System	20 Apr 2021 18:09:50
User entered 'magnesium replacement'	Erica Osmundsen (b) (4) (b) (4)	20 Apr 2021 18:08:59

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:41:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	20 Apr 2021 18:08:59
	(b) (4)	
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:41:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered 'electrolyte abnormalities'	Erica Osmundsen (b) (4)	20 Apr 2021 18:08:59

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:41:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered '1'	Erica Osmundsen (b) (4)	20 Apr 2021 18:08:59

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:41:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'Other (OTHER)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 18:08:59

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:41:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered 'g/hr'	Erica Osmundsen (b) (4)	20 Apr 2021 18:08:59
	(b) (4)	
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:41:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'as needed (PRN)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 18:08:59

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:41:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	20 Apr 2021 18:08:59
	(b) (4)	
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:41:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 18:08:59

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:41:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	20 Apr 2021 18:08:59
	(b) (4)	
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:41:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered '08 Apr 2021'	Erica Osmundsen (b) (4)	20 Apr 2021 18:08:59

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:41:52

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered '0'	Erica Osmundsen (b) (4)	20 Apr 2021 18:08:59

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:41:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	20 Apr 2021 18:08:59
	(b) (4)	
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:41:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered '09 Apr 2021'	Erica Osmundsen (b) (4)	20 Apr 2021 18:08:59
	(b) (4)	
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:41:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	20 Apr 2021 18:08:59
	(b) (4)	
	(b) (4)	

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:41:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 18:08:59

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 18:08:59

US3202395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:41:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 18:08:59

US3202395

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:41:52

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:13:18
	(b) (4)	
User entered 'No (N)'	zackery harmon (b) (4)	12 Sep 2020 16:15:31
	(b) (4)	

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:18:41
User entered 'USA-US128-2021-MRNA-1273-P301000018'	System	13 Apr 2021 13:18:09

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:18:41
User entered 'Yes (Y)'	System	13 Apr 2021 13:18:09

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:18:41
User entered 'No (N)'	System	13 Apr 2021 13:18:09

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:18:41
User entered 'No (N)'	System	13 Apr 2021 13:18:09

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:18:41
User entered 'Yes (Y)'	System	13 Apr 2021 13:18:09

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:18:41
User entered 'No (N)'	System	13 Apr 2021 13:18:09

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:18:41
User entered 'No (N)'	System	13 Apr 2021 13:18:09

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:18:41
User entered 'No (N)'	System	13 Apr 2021 13:18:09

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:18:41
User entered 'Mark'	System	13 Apr 2021 13:18:09

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:18:41
User entered 'McKenzie'	System	13 Apr 2021 13:18:09

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 16:08:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
User entered 'US'	(b) (4) System	13 Apr 2021 13:18:49

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	21 Apr 2021 13:35:59
User entered '2'	System	20 Apr 2021 16:08:39
User entered '1'	System	13 Apr 2021 13:18:49

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:18:41
User entered 'USA-US128-2021-MRNA-1273-P301000018'	System	13 Apr 2021 13:18:09

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:18:41
User entered 'Yes (Y)'	System	13 Apr 2021 13:18:09

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:18:41
User entered 'No (N)'	System	13 Apr 2021 13:18:09

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:18:41
User entered 'No (N)'	System	13 Apr 2021 13:18:09

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:18:41
User entered 'Yes (Y)'	System	13 Apr 2021 13:18:09

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:18:41
User entered 'No (N)'	System	13 Apr 2021 13:18:09

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:18:41
User entered 'No (N)'	System	13 Apr 2021 13:18:09

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:18:41
User entered 'No (N)'	System	13 Apr 2021 13:18:09

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:18:41
User entered 'Mark'	System	13 Apr 2021 13:18:09

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:18:41
User entered 'McKenzie'	System	13 Apr 2021 13:18:09

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 16:08:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
User entered 'US'	(b) (4) System	13 Apr 2021 13:18:49

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	21 Apr 2021 13:35:59
User entered '2'	System	20 Apr 2021 16:08:39
User entered '1'	System	13 Apr 2021 13:18:49

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:41:52

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
User entered '13/Apr/2021 06:18'	(b) (4) System	13 Apr 2021 13:18:49

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:41:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 16:08:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
User entered '1'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:18:49

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:18:41
User entered 'USA-US128-2021-MRNA-1273-P301000018'	System	13 Apr 2021 13:18:09

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:18:41
User entered 'Yes (Y)'	System	13 Apr 2021 13:18:09

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:18:41
User entered 'No (N)'	System	13 Apr 2021 13:18:09

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:18:41
User entered 'No (N)'	System	13 Apr 2021 13:18:09

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:18:41
User entered 'Yes (Y)'	System	13 Apr 2021 13:18:09

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:18:41
User entered 'No (N)'	System	13 Apr 2021 13:18:09

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:18:41
User entered 'No (N)'	System	13 Apr 2021 13:18:09

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:18:41
User entered 'No (N)'	System	13 Apr 2021 13:18:09

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:18:41
User entered 'Mark'	System	13 Apr 2021 13:18:09

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:18:41
User entered 'McKenzie'	System	13 Apr 2021 13:18:09

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 16:08:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
User entered 'US'	(b) (4) System	13 Apr 2021 13:18:49

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	21 Apr 2021 13:35:59
User entered '2'	System	20 Apr 2021 16:08:39
User entered '1'	System	13 Apr 2021 13:18:49

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:41:52

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '20/Apr/2021 12:08'	(b) (4) System	20 Apr 2021 16:08:39

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:41:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '1'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:39

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:18:41
User entered 'USA-US128-2021-MRNA-1273-P301000018'	System	13 Apr 2021 13:18:09

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:18:41
User entered 'Yes (Y)'	System	13 Apr 2021 13:18:09

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:18:41
User entered 'No (N)'	System	13 Apr 2021 13:18:09

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:18:41
User entered 'No (N)'	System	13 Apr 2021 13:18:09

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:18:41
User entered 'Yes (Y)'	System	13 Apr 2021 13:18:09

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:18:41
User entered 'No (N)'	System	13 Apr 2021 13:18:09

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:18:41
User entered 'No (N)'	System	13 Apr 2021 13:18:09

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:18:41
User entered 'No (N)'	System	13 Apr 2021 13:18:09

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:18:41
User entered 'Mark'	System	13 Apr 2021 13:18:09

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:18:41
User entered 'McKenzie'	System	13 Apr 2021 13:18:09

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 16:08:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:18
User entered 'US'	(b) (4) System	13 Apr 2021 13:18:49

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	21 Apr 2021 13:35:59
User entered '2'	System	20 Apr 2021 16:08:39
User entered '1'	System	13 Apr 2021 13:18:49

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:41:52

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered '21/Apr/2021 09:35'	(b) (4) System	21 Apr 2021 13:35:59

US3202395

Folder: SAE USA-US128-2021-MRNA-1273-P301000018

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:41:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:04:06
User entered 'I'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:35:59