

US3832150 (Prod: Keystone VitaLink Research - Anderson - PPDS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:04:59

All time stamps listed in this document are displayed in GMT

US3832150

Form: Participant Creation

Data signed: (b) (4) 21 Feb 2021 17:13:47

Generated On: 10 Jun 2021 10:04:59

[Participant ID](#)

US3832150

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

US3832150

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 14:17:51

Generated On: 10 Jun 2021 10:04:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3832150

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 14:17:42

Generated On: 10 Jun 2021 10:04:59

Date of Birth (MMM yyyy)	(b) (6) 1959
Age	61
Age Units	YEARS
Age (Derived)	61
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) 15 Feb 2021 14:17:42

Generated On: 10 Jun 2021 10:04:59

Date of Informed Consent (<i>dd MMM yyyy</i>)	10 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 14:17:51

Generated On: 10 Jun 2021 10:04:59

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 14:17:51

Generated On: 10 Jun 2021 10:04:59

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 29 Apr 2021 02:21:24

Generated On: 10 Jun 2021 10:04:59

Condition	BRONCHIECTASIS
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 29 Apr 2021 02:21:24

Generated On: 10 Jun 2021 10:04:59

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Start Year (derived)	2009
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 29 Apr 2021 02:21:24

Generated On: 10 Jun 2021 10:04:59

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 29 Apr 2021 02:21:24

Generated On: 10 Jun 2021 10:04:59

Condition	OVARIAN CYST
Start date (dd MMM yyyy)	UN UNK 1986
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 1987
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1986
Start Year (derived)	1986
Stop Month and Year (derived)	JAN 1987
Stop Year (derived)	1987

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 29 Apr 2021 02:21:24

Generated On: 10 Jun 2021 10:04:59

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Start Year (derived)	2009
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 29 Apr 2021 02:21:24

Generated On: 10 Jun 2021 10:04:59

Condition	POST MENOPAUSAL
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 (7)

Data signed: (b) (4) 29 Apr 2021 02:21:24

Generated On: 10 Jun 2021 10:04:59

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 29 Apr 2021 02:21:24

Generated On: 10 Jun 2021 10:04:59

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 29 Apr 2021 02:21:24

Generated On: 10 Jun 2021 10:04:59

Condition	AORTIC VALVE REPLACEMENT
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 29 Apr 2021 02:21:24

Generated On: 10 Jun 2021 10:04:59

Condition	OOPHORECTOMY
Start date (dd MMM yyyy)	UN UNK 1987
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 1987
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1987
Start Year (derived)	1987
Stop Month and Year (derived)	JAN 1987
Stop Year (derived)	1987

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 29 Apr 2021 02:21:24

Generated On: 10 Jun 2021 10:04:59

Condition	APPENDECTOMY
Start date (dd MMM yyyy)	UN UNK 1987
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 1987
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1987
Start Year (derived)	1987
Stop Month and Year (derived)	JAN 1987
Stop Year (derived)	1987

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 29 Apr 2021 02:21:24

Generated On: 10 Jun 2021 10:04:59

Condition	APPENDICITIS
Start date (dd MMM yyyy)	UN UNK 1987
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 1987
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1987
Start Year (derived)	1987
Stop Month and Year (derived)	JAN 1987
Stop Year (derived)	1987

US3832150

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 14:17:51

Generated On: 10 Jun 2021 10:04:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 AUG 2020
Time of assessment (00:00-23:59)	15:58 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 15:58
Height (xxx.x)	163.8 cm
Weight (xxx.x)	58.1 kg
BMI (xxx.x)	21.65451 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 14:17:51

Generated On: 10 Jun 2021 10:04:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 14:17:42

Generated On: 10 Jun 2021 10:04:59

Date of assessment (dd MMM yyyy) 10 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 2008

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 14:17:51

Generated On: 10 Jun 2021 10:04:59

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) 15 Feb 2021 14:17:51

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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)	False
Other	True
Specify	PARTICIPANT ATTENDED LARGE GROUP EVENTS IN THE PAST FEW WEEKS (E.G., WEDDING, PLACES OF WORSHIP, CONCERT)

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 14:17:51

Generated On: 10 Jun 2021 10:04:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 14:17:51

Generated On: 10 Jun 2021 10:04:59

What was the date of randomization? (dd MMM yyyy) 10 AUG 2020

What was the participant's randomization number? 143573

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☐
 >=18 and <65 years and at risk ☒
 >=65 years ☐

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☒
 No ☐

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☒
 No ☐

Severe obesity (body mass index > or = 40kg/m2) Yes ☐
 No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐
 No ☒

Liver Disease Yes ☐
 No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 14:17:51

Generated On: 10 Jun 2021 10:04:59

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) 15 Feb 2021 14:17:51

Generated On: 10 Jun 2021 10:04:59

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 AUG 2020
Time of assessment (00:00-23:59)	15:58 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 15:58
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 14:17:51

Generated On: 10 Jun 2021 10:04:59

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	10 AUG 2020
Time of assessment (00:00-23:59)	17:05 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 17:05
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	61 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)	73 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 14:17:51

Generated On: 10 Jun 2021 10:04:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 14:17:51

Generated On: 10 Jun 2021 10:04:59

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) 10 AUG 2020

What was the treatment time? (00:00-23:59) 16:39 (24 HR)

Treatment Date and Time (derived) 10 AUG 2020 16:39

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) 15 Feb 2021 14:17:51

Generated On: 10 Jun 2021 10:04:59

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

10 AUG 2020

Collection time (00:00-23:59)

16:12 (24 HR)

Collection date and time (derived)

10 AUG 2020 16:12

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 14:17:51

Generated On: 10 Jun 2021 10:04:59

Collection date (dd MMM yyyy)			10 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:10	10 AUG 2020 16:10
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:17:51

Generated On: 10 Jun 2021 10:04:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

10 AUG 2020 17:10

PC Open Date & Time

10 AUG 2020 16:59

PC Close Date & Time

10 AUG 2020 19:29

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.6 °F

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

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

PC Time Stamp	10 AUG 2020 21:40
PC Open Date & Time	10 AUG 2020 20:24
PC Close Date & Time	11 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 15:25

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 15:05

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 13:38

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 21:00

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 21:02

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

16 AUG 2020 19:46

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

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

10 AUG 2020 17:11

PC Open Date & Time

10 AUG 2020 16:59

PC Close Date & Time

10 AUG 2020 19:29

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

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

10 AUG 2020 21:41

PC Open Date & Time

10 AUG 2020 20:24

PC Close Date & Time

11 AUG 2020 11:59

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 15:26

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 15:06

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 13:38

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 21:00

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 21:03

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 19:47

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

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 ☐

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 17:12
PC Open Date & Time	10 AUG 2020 16:59
PC Close Date & Time	10 AUG 2020 19:29

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

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 ☐

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 21:41
PC Open Date & Time	10 AUG 2020 20:24
PC Close Date & Time	11 AUG 2020 11:59

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:59

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 15:26
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

56 of 2442

EAB) (1725)

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:59

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 15:08
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:59

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 ☒

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:59

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 13:40
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:59

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 ☒

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:59

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 21:01
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

62 of 2442

EAB) (1725)

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:59

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 21:03
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

64 of 2442

EAB) (1725)

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:59

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 19:47
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3832150

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 14:17:42

Generated On: 10 Jun 2021 10:04:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832150

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:17:42

Generated On: 10 Jun 2021 10:04:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832150

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832150

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832150

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832150

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832150

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 14:17:52

Generated On: 10 Jun 2021 10:04:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3832150

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 14:17:52

Generated On: 10 Jun 2021 10:04:59

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)	9 SEP 2020
Time of assessment (00:00-23:59)	16:05 (24 HR)
Vital Signs Date and Time (derived)	9 SEP 2020 16:05
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3832150

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 14:17:52

Generated On: 10 Jun 2021 10:04:59

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	9 SEP 2020
Time of assessment (00:00-23:59)	17:00 (24 HR)
Vital Signs Date and Time (derived)	9 SEP 2020 17:00
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3832150

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 14:17:52

Generated On: 10 Jun 2021 10:04:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 SEP 2020

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

US3832150

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 14:17:52

Generated On: 10 Jun 2021 10:04:59

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) 9 SEP 2020

What was the treatment time? (00:00-23:59) 16:30 (24 HR)

Treatment Date and Time (derived) 9 SEP 2020 16:30

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

US3832150

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 14:17:52

Generated On: 10 Jun 2021 10:04:59

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

9 SEP 2020

Collection time (00:00-23:59)

16:27 (24 HR)

Collection date and time (derived)

9 SEP 2020 16:27

US3832150

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 14:17:52

Generated On: 10 Jun 2021 10:04:59

Collection date (dd MMM yyyy)			9 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:19	9 SEP 2020 16:19
Nasopharyngeal Swab 2	No		

US3832150

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:17:52

Generated On: 10 Jun 2021 10:04:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 17:02

PC Open Date & Time

09 SEP 2020 16:50

PC Close Date & Time

09 SEP 2020 19:20

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

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

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 09 SEP 2020 20:15

PC Close Date & Time 10 SEP 2020 11:59

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 21:04

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

11 SEP 2020 18:56

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 21:49

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

13 SEP 2020 20:31

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:04:59

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.

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 21:00

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 20:50

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 17:02

PC Open Date & Time

09 SEP 2020 16:50

PC Close Date & Time

09 SEP 2020 19:20

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

09 SEP 2020 20:15

PC Close Date & Time

10 SEP 2020 11:59

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 21:04

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 18:56

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 21:50

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 20:31

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 21:00

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 20:50

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

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 ☐

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 17:03
PC Open Date & Time	09 SEP 2020 16:50
PC Close Date & Time	09 SEP 2020 19:20

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

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 ☐

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

09 SEP 2020 20:15

PC Close Date & Time

10 SEP 2020 11:59

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:59

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 21:05
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:59

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 18:57
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:59

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 ☒

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:59

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 21:50
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:59

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 ☒

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EAB) (1725)

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:59

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 20:32
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:59

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 21:01
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:59

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 20:51
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3832150

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832150

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832150

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 14:17:42

Generated On: 10 Jun 2021 10:04:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832150

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:17:42

Generated On: 10 Jun 2021 10:04:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832150

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 14:17:42

Generated On: 10 Jun 2021 10:04:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832150

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:17:42

Generated On: 10 Jun 2021 10:04:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832150

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 14:17:52

Generated On: 10 Jun 2021 10:04:59

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	VISIT3

US3832150

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 14:17:52

Generated On: 10 Jun 2021 10:04:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	7 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	15:51 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 15:51
Temperature (<i>xxx.x</i>)	97.7 F
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>)	12 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>)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3832150

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 14:17:52

Generated On: 10 Jun 2021 10:04:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 OCT 2020

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

US3832150

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 14:17:52

Generated On: 10 Jun 2021 10:04:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	7 OCT 2020
Collection time (00:00-23:59)	16:03 (24 HR)
Collection date and time (derived)	7 OCT 2020 16:03

US3832150

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:17:52

Generated On: 10 Jun 2021 10:04:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

11 OCT 2020 20:48:47

Patient Cloud Open Date & Time

10 OCT 2020 00:01

Patient Cloud Close Date & Time

14 OCT 2020 23:59

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

18 OCT 2020 09:26:04

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

25 OCT 2020 07:38:35

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 NOV 2020 12:27:39

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	True
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	14 NOV 2020 08:17:30
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	21 NOV 2020 07:51:26
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 NOV 2020 07:22:42

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2020 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 DEC 2020 06:38:55

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

Date and time of submission

16 DEC 2020 12:37:18

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 DEC 2020 13:10:07

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 DEC 2020 08:14:43

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

06 JAN 2021 17:26:51

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 JAN 2021 19:25:17

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 JAN 2021 12:20:59

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

29 JAN 2021 10:50:23

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

03 FEB 2021 07:48:21

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 FEB 2021 12:09:06

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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	17 FEB 2021 08:22:30
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 FEB 2021 02:31:18

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 MAR 2021 11:59:34

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 MAR 2021 10:11:56

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 MAR 2021 09:21:22

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 MAR 2021 06:44:12

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 MAR 2021 06:42:51

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 APR 2021 08:19:15

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 APR 2021 20:56:44

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 08:43:56

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

Date and time of submission

01 MAY 2021 15:16:34

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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 ☐

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

Date and time of submission	
Patient Cloud Open Date & Time	05 MAY 2021 00:01
Patient Cloud Close Date & Time	09 MAY 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 MAY 2021 00:01
Patient Cloud Close Date & Time	16 MAY 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 285

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 334

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

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

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

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

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

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

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 341

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

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

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

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

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

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

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 348

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

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

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

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

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

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

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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 ☐

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

11 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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 ☐

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 AUG 2021 00:01
Patient Cloud Close Date & Time	29 AUG 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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 ☐

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 SEP 2021 00:01
Patient Cloud Close Date & Time	05 SEP 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 SEP 2021 00:01
Patient Cloud Close Date & Time	19 SEP 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

13 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 439

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

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

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

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

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

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

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

Patient Cloud Open Date & Time	20 OCT 2021 00:01
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Patient Cloud Close Date & Time	24 OCT 2021 23:59
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US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 446

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

10 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 467

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 DEC 2021 00:01
Patient Cloud Close Date & Time	05 DEC 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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 ☐

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

08 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 DEC 2021 00:01
Patient Cloud Close Date & Time	19 DEC 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 DEC 2021 00:01
Patient Cloud Close Date & Time	26 DEC 2021 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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 ☐

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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 ☐

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 FEB 2022 00:01
Patient Cloud Close Date & Time	27 FEB 2022 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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 ☐

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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 ☐

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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 ☐

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 621

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

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

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

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

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

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

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

20 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 628

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

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

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

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

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

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

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

15 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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 ☐

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 JUL 2022 00:01
Patient Cloud Close Date & Time	10 JUL 2022 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 JUL 2022 00:01
Patient Cloud Close Date & Time	17 JUL 2022 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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 ☐

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 719

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

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

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

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

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

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

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 JUL 2022 00:01
Patient Cloud Close Date & Time	31 JUL 2022 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 733

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

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

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

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

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

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

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

14 AUG 2022 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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 ☐

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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 ☐

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

Date and time of submission

Patient Cloud Open Date & Time	05 OCT 2022 00:01
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Patient Cloud Close Date & Time	09 OCT 2022 23:59
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US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

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

Date and time of submission	
Patient Cloud Open Date & Time	12 OCT 2022 00:01
Patient Cloud Close Date & Time	16 OCT 2022 23:59

US3832150

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 10:04:59

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		02 MAR 2021 16:11:59

US3832150

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832150

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832150

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832150

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832150

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832150

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832150

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832150

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832150

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 23:10:56

Generated On: 10 Jun 2021 10:04:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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	VISIT4

US3832150

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 23:10:56

Generated On: 10 Jun 2021 10:04:59

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) _____

US3832150

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 23:10:56

Generated On: 10 Jun 2021 10:04:59

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.

US3832150

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 23:10:56

Generated On: 10 Jun 2021 10:04:59

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 MAR 2021

Collection time (00:00-23:59)

13:26 (24 HR)

Collection date and time (derived)

11 MAR 2021 13:26

US3832150

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 23:10:55

Generated On: 10 Jun 2021 10:04:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832150

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 23:10:55

Generated On: 10 Jun 2021 10:04:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832150

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 23:10:55

Generated On: 10 Jun 2021 10:04:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832150

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

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

US3832150

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:59

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

Date of Contact	16 NOV 2020
Time of Contact	09:00
Date and Time of Contact (derived)	16 NOV 2020 09:00
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"/>

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	97.0 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	17 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.6 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

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

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3832150

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 29 Apr 2021 02:21:23

Generated On: 10 Jun 2021 10:04:59

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	18 NOV 2020
Day 5	Yes	20 NOV 2020
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)	

US3832150

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3832150

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 NOV 2020
Time of assessment (00:00-23:59)	11:36 (24 HR)
Vital Signs Date and Time (derived)	16 NOV 2020 11:36
Height (xxx.x)	163.8 cm
Weight (xxx.x)	58.4 kg
Temperature (xxx.x)	97.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3832150

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 NOV 2020

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

US3832150

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

16 NOV 2020

US3832150

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

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

US3832150

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

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) _____

US3832150

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

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.

US3832150

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 21 Feb 2021 17:13:47

Generated On: 10 Jun 2021 10:04:59

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☒

Date of Collection

US3832150

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

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

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

Visit date (dd MMM yyyy)	13 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3832150

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

Form: Unblinding

Data signed: (b) (4) 12 Apr 2021 23:10:55

Generated On: 10 Jun 2021 10:04:59

Date of updated informed consent (<i>dd MMM yyyy</i>)	13 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	13 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3832150

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

Height	64.5 in
Weight	126.8 lb
BMI (xxx.x)	21.47384

US3832150

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

Height	64.5 in
Weight	126.8 lb
BMI (xxx.x)	21.47384
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)	13 JAN 2021
Time of assessment (00:00-23:59)	08:06 (24 HR)
Vital Signs Date and Time (derived)	13 JAN 2021 08:06
Temperature (xxx.x)	97.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

US3832150

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

Height	64.5 in
Weight	126.8 lb
BMI (xxx.x)	21.47384
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)	13 JAN 2021
Time of assessment (00:00-23:59)	08:55 (24 HR)
Vital Signs Date and Time (derived)	13 JAN 2021 08:55
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3832150

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

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 JAN 2021

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

US3832150

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

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

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) 13 JAN 2021

What was the treatment time? (00:00-23:59) 08:24 (24 HR)

Treatment Date and Time (derived) 13 JAN 2021 08:24

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

US3832150

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 JAN 2021

Collection time (00:00-23:59)

08:02 (24 HR)

Collection date and time (derived)

13 JAN 2021 08:02

US3832150

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 JAN 2021

Collection time (00:00 - 23:59)

07:58

Collection Date and Time (derived)

13 JAN 2021 07:58

US3832150

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

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832150

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

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

US3832150

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3832150

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

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)	10 FEB 2021
Time of assessment (00:00-23:59)	12:09 (24 HR)
Vital Signs Date and Time (derived)	10 FEB 2021 12:09
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3832150

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

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)	10 FEB 2021
Time of assessment (00:00-23:59)	12:52 (24 HR)
Vital Signs Date and Time (derived)	10 FEB 2021 12:52
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3832150

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 FEB 2021

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

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Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

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) 10 FEB 2021

What was the treatment time? (00:00-23:59) 12:19 (24 HR)

Treatment Date and Time (derived) 10 FEB 2021 12:19

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3832150

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832150

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832150

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:13:48

Generated On: 10 Jun 2021 10:04:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832150

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 23:10:55

Generated On: 10 Jun 2021 10:04:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3832150

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 23:10:55

Generated On: 10 Jun 2021 10:04:59

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) _____

US3832150

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 23:10:55

Generated On: 10 Jun 2021 10:04:59

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.

US3832150

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 23:10:55

Generated On: 10 Jun 2021 10:04:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 MAR 2021
Collection time (00:00-23:59)	13:26 (24 HR)
Collection date and time (derived)	11 MAR 2021 13:26

US3832150

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 21 Feb 2021 17:13:47

Generated On: 10 Jun 2021 10:04:59

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 02:21:23

Generated On: 10 Jun 2021 10:04:59

AEID USA-US100-2021-MRNA-1273-P30
1000008

Adverse event ENDOMETRIOID CARCINOMA

Was this a medically-attended AE? Yes ☒
No ☐

Was this a Solicited Adverse Reaction? Yes ☐
No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes ☐
No ☒

Start date (dd MMM yyyy) UN OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy) 18 JAN 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 (1)

Data signed: (b) (4) 29 Apr 2021 02:21:23

Generated On: 10 Jun 2021 10:04:59

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

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 02:21:23

Generated On: 10 Jun 2021 10:04:59

61 Y/O FEMALE RANDOMIZED
TO ACTIVE IP ON 1/13/2021
LAST DOSE OF IP 2/10/2021
WITH A HISTORY OF AORTIC
VALVE PLACEMENT 2012 AND
OVARIAN CYST REMOVAL.
SUBJECT REPORTED HAVING A
D AND C AFTER EXPERIENCING
POST-MENOPAUSAL BLEEDING
IN OCT OF 2020. ENDOMETRIAL
BIOPSY DONE IN DEC 2020
AFTER ULTRASOUND SHOWED
THICKENING OF THE
ENDOMETRIAL STRIPE.
PATHOLOGY SHOWED
ATYPICAL PAPILLARY
ENDOMETRIAL
PROLIFERATION SUSPICIOUS
FOR ENDOMETRIOID
ADENOCARCINOMA. SUBJECT
AGREED TO A TAH/BSO.
PATHOLOGY FROM TAH/BSO
COMPLETED 1/18/2021 NOTED
ENDOMETRIAL CANCER.
SUBJECT HAD A PET SCAN
DONE 2/3/2021 TO COMPLETE
EVALUATION OF NOTED
MALIGNANT HIGH GRADE AND
SITES DX. INCLUDING
WASHINGS, DEEP INVASIONS,
ALONG WITH SITES FREE OF
DX. PET SCAN NOTED NO
EVIDENCE OF
HYPERMETABOLIC RESIDUAL
OR METASTATIC DISEASE.
SUBJECT TO HAVE A CA125
EVERY 3 WEEKS AND IS BEING
MONITORED CLOSELY.

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)	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 02:21:23

Generated On: 10 Jun 2021 10:04:59

AEID	
Adverse event	POST MENOPAUSAL BLEEDING
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	UN 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)	18 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 02:21:23

Generated On: 10 Jun 2021 10:04:59

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Apr 2021 02:21:23

Generated On: 10 Jun 2021 10:04:59

AEID	
Adverse event	VIRAL ILLNESS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	11 NOV 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)	13 NOV 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) 29 Apr 2021 02:21:23

Generated On: 10 Jun 2021 10:04:59

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 21 Feb 2021 17:13:47

Generated On: 10 Jun 2021 10:04:59

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

Yes ☒

No ☐

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

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 21 Feb 2021 17:13:47

Generated On: 10 Jun 2021 10:04:59

Name of Medication VIBERZI

Prophylaxis Yes ☐
No ☒

Indication COLITIS

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 21 Feb 2021 17:13:47

Generated On: 10 Jun 2021 10:04:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 21 Feb 2021 17:13:47

Generated On: 10 Jun 2021 10:04:59

Name of Medication SERTRALINE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

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) 21 Feb 2021 17:13:47

Generated On: 10 Jun 2021 10:04:59

	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 2009	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 21 Feb 2021 17:13:47

Generated On: 10 Jun 2021 10:04:59

Name of Medication CLONAZEPAM

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 21 Feb 2021 17:13:47

Generated On: 10 Jun 2021 10:04:59

	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 2009	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 21 Feb 2021 17:13:47

Generated On: 10 Jun 2021 10:04:59

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC 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 ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 21 Feb 2021 17:13:47

Generated On: 10 Jun 2021 10:04:59

	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 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 21 Feb 2021 17:13:47

Generated On: 10 Jun 2021 10:04:59

Name of Medication VENTOLIN HFA

Prophylaxis Yes ☐
No ☒

Indication BRONCHIECTASIS

Dose per administration 90

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

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 21 Feb 2021 17:13:47

Generated On: 10 Jun 2021 10:04:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 21 Feb 2021 17:13:47

Generated On: 10 Jun 2021 10:04:59

Name of Medication DULERA

Prophylaxis Yes ☐
No ☒

Indication BRONCHIECTASIS

Dose per administration 100/5

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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US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 21 Feb 2021 17:13:47

Generated On: 10 Jun 2021 10:04:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 21 Feb 2021 17:13:47

Generated On: 10 Jun 2021 10:04:59

Name of Medication BENADRYL

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIC RHINITIS

Dose per administration 25

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 21 Feb 2021 17:13:47

Generated On: 10 Jun 2021 10:04:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3832150

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 21 Feb 2021 17:13:47

Generated On: 10 Jun 2021 10:04:59

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3832150

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 29 Apr 2021 02:21:23

Generated On: 10 Jun 2021 10:04:59

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
18 JAN 2021	TOTAL ABDOMINAL HYSTERECTOMY AND BILATERAL SALPINGO OOPHORECTOMY	Adverse Event	
UN OCT 2020	DILATION AND CURETTAGE	Adverse Event	
UN DEC 2020	VAGINAL ULTRASOUND	Adverse Event	
UN DEC 2020	ENDOMETRIAL BIOPSY	Diagnostic	
03 FEB 2021	PET CT OF SKULL AND MID THIGH	Adverse Event	

US3832150

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:04:59

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

US3832150

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:04:59

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 ☐

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: (b) (4) 29 Apr 2021 02:21:23

Generated On: 10 Jun 2021 10:04:59

SAEID	USA-US100-2021-MRNA-1273-P301000008
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Apr 2021 02:21:23

Generated On: 10 Jun 2021 10:04:59

SAEID	USA-US100-2021-MRNA-1273-P301000008
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	01/FEB/2021 15:58
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

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Data signed: (b) (4) 29 Apr 2021 02:21:23

Generated On: 10 Jun 2021 10:04:59

SAEID	USA-US100-2021-MRNA-1273-P301000008
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	10/FEB/2021 12:42
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

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Data signed: (b) (4) 29 Apr 2021 02:21:23

Generated On: 10 Jun 2021 10:04:59

SAEID	USA-US100-2021-MRNA-1273-P301000008
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	17/FEB/2021 08:44
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

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form (4)

Data signed: (b) (4) 29 Apr 2021 02:21:23

Generated On: 10 Jun 2021 10:04:59

SAEID	USA-US100-2021-MRNA-1273-P301000008
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	02/MAR/2021 15:14
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

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form (5)

Data signed: (b) (4) 29 Apr 2021 02:21:23

Generated On: 10 Jun 2021 10:04:59

SAEID	USA-US100-2021-MRNA-1273-P301000008
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	04/MAR/2021 11:34
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

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form (6)

Data signed: (b) (4) 29 Apr 2021 02:21:23

Generated On: 10 Jun 2021 10:04:59

SAEID	USA-US100-2021-MRNA-1273-P301000008
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	25/MAR/2021 09:31
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

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form (7)

Data signed: (b) (4) 29 Apr 2021 02:21:23

Generated On: 10 Jun 2021 10:04:59

SAEID	USA-US100-2021-MRNA-1273-P301000008
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	21/APR/2021 10:06
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

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form (8)

Data signed: (b) (4) 29 Apr 2021 02:21:23

Generated On: 10 Jun 2021 10:04:59

SAEID	USA-US100-2021-MRNA-1273-P301000008
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	21/APR/2021 09:26
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3832150 (Prod: Keystone VitaLink Research - Anderson - PPDS)

US3832150

Form: Participant Creation

Generated On: 10 Jun 2021 10:04:59

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'US3832150'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 19:44:26

US3832150

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:04:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 19:50:23

US3832150

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:04:59

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '10 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 19:44:27

US3832150

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:04:59

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Clinic (Clinic)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 19:50:23

US3832150

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:04:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered 'SCRN'	System	10 Aug 2020 19:50:23

US3832150

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:04:59

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered (b) (6) 1959'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 19:44:28

US3832150

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:04:59

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered '61'	(b) (4) Alyssa-Kay Peay (b) (4)	10 Aug 2020 19:50:41

US3832150

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:04:59

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered 'YEARS'	System	10 Aug 2020 19:50:41

US3832150

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:04:59

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered '61'	System	10 Aug 2020 19:51:26

US3832150

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:04:59

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered 'Female (F)'	(b) (4) Alyssa-Kay Peay (b) (4)	10 Aug 2020 19:50:41

US3832150

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:04:59

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 19:50:41

US3832150

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:04:59

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered 'I'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 19:50:41

US3832150

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:04:59

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered '0'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 19:50:41

US3832150

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:04:59

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered '0'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 19:50:41

US3832150

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:04:59

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered '0'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 19:50:41

US3832150

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:04:59

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered '0'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 19:50:41

US3832150

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:04:59

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered '0'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 19:50:41

US3832150

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:04:59

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered empty.	Alyssa-Kay Peay (b) (4)	10 Aug 2020 19:50:41

US3832150

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:04:59

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered '0'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 19:50:41

US3832150

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:04:59

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered '0'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 19:50:41

US3832150

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:04:59

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered '10 Aug 2020'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 19:51:26

US3832150

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:04:59

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered 'Aug 2020'	System	10 Aug 2020 19:51:26

US3832150

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:04:59

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered '2020'	System	10 Aug 2020 19:51:26

US3832150

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:04:59

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered 'Amendment 1 (1)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 19:51:26

US3832150

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:04:59

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 19:51:26

US3832150

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:04:59

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered empty.	Alyssa-Kay Peay (b) (4)	10 Aug 2020 19:51:26

US3832150

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:04:59

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered empty.	Alyssa-Kay Peay (b) (4)	10 Aug 2020 19:51:26

US3832150

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:04:59

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 19:51:26

US3832150

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:04:59

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 19:44:27

US3832150

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:04:59

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered 'I'	System	10 Aug 2020 20:12:20

US3832150

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:04:59

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:12:20

US3832150

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:04:59

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:12:27

US3832150

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:04:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchial conditions NEC, PT: Bronchiectasis, LLT: Bronchiectasis - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 22:28:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 22:28:40
Data point term sent to Coder	System	10 Aug 2020 20:13:19
User entered 'Bronchiectasis'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:12:56

US3832150

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:04:59

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'un UNK 2016'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:12:56

US3832150

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '0'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:12:56

US3832150

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:04:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:12:56

US3832150

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:04:59

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered empty.	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:12:56

US3832150

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:04:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '0'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:12:56

US3832150

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:04:59

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered 'Jan 2016'	System	10 Aug 2020 20:12:56

US3832150

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:04:59

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered '2016'	System	10 Aug 2020 20:12:56

US3832150

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:04:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered empty.	System	10 Aug 2020 20:12:56

US3832150

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:04:59

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered empty.	System	10 Aug 2020 20:12:56

US3832150

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:04:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 22:29:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 22:29:08
Data point term sent to Coder	System	10 Aug 2020 20:13:20
User entered 'Anxiety'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:13:10

US3832150

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:04:59

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'un UNK 2009'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:13:10

US3832150

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '0'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:13:10

US3832150

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:04:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:13:10

US3832150

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:04:59

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered empty.	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:13:10

US3832150

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:04:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '0'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:13:10

US3832150

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:04:59

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered 'Jan 2009'	System	10 Aug 2020 20:13:10

US3832150

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:04:59

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered '2009'	System	10 Aug 2020 20:13:10

US3832150

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:04:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered empty.	System	10 Aug 2020 20:13:10

US3832150

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:04:59

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered empty.	System	10 Aug 2020 20:13:10

US3832150

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:04:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User coded data point as SOC: Cardiac disorders, HLT: Cardiac valve disorders, HLT: Cardiac valve disorders NEC, PT: Heart valve incompetence, LLT: Cardiac valve leak - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:21:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:21:34
Data point term sent to Coder	System	10 Aug 2020 20:14:21
User entered 'Leaky aortic valve'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:13:27

US3832150

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:04:59

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'un UNK 2012'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:13:27

US3832150

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '0'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:13:27

US3832150

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:04:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:13:27

US3832150

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:04:59

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered empty.	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:13:27

US3832150

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:04:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '0'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:13:27

US3832150

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:04:59

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered 'Jan 2012'	System	10 Aug 2020 20:13:27

US3832150

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:04:59

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered '2012'	System	10 Aug 2020 20:13:27

US3832150

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:04:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered empty.	System	10 Aug 2020 20:13:27

US3832150

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:04:59

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered empty.	System	10 Aug 2020 20:13:27

US3832150

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:04:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Ovarian and fallopian tube disorders, HLT: Ovarian and fallopian tube cysts and neoplasms, PT: Ovarian cyst, LLT: Ovarian cyst - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 22:28:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 22:28:41
Data point term sent to Coder	System	10 Aug 2020 20:14:22
User entered 'Ovarian cyst'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:13:45

US3832150

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:04:59

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'un UNK 1986'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:13:45

US3832150

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '0'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:13:45

US3832150

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:04:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:13:45

US3832150

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:04:59

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'un UNK 1987'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:13:45

US3832150

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:04:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '0'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:13:45

US3832150

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:04:59

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered 'Jan 1986'	System	10 Aug 2020 20:13:45

US3832150

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:04:59

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered '1986'	System	10 Aug 2020 20:13:45

US3832150

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:04:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered 'Jan 1987'	System	10 Aug 2020 20:13:45

US3832150

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:04:59

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered '1987'	System	10 Aug 2020 20:13:45

US3832150

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:04:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	07 Oct 2020 20:41:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Oct 2020 20:41:14
Data point term sent to Coder	System	07 Oct 2020 20:16:15
User entered 'Insomnia'	Emma Partin (b) (4)	07 Oct 2020 20:15:32
	(b) (4)	

US3832150

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:04:59

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'un UNK 2009'	Emma Partin (b) (4)	07 Oct 2020 20:15:32

US3832150

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '0'	Emma Partin (b) (4)	07 Oct 2020 20:15:32

US3832150

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:04:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Yes (Y)'	Emma Partin (b) (4)	07 Oct 2020 20:15:32

US3832150

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:04:59

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered empty.	Emma Partin (b) (4)	07 Oct 2020 20:15:32

US3832150

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:04:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '0'	Emma Partin (b) (4)	07 Oct 2020 20:15:32

US3832150

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:04:59

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered 'Jan 2009'	System	07 Oct 2020 20:15:32

US3832150

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:04:59

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered '2009'	System	07 Oct 2020 20:15:32

US3832150

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:04:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered empty.	System	07 Oct 2020 20:15:32

US3832150

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:04:59

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered empty.	System	07 Oct 2020 20:15:32

US3832150

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:04:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 14:16:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 14:16:30
Data point term sent to Coder	System	21 Oct 2020 14:15:34
User entered 'Post Menopausal'	Alyssa-Kay Peay (b) (4)	21 Oct 2020 14:14:50

US3832150

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:04:59

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'UN UNK 2008'	Alyssa-Kay Peay (b) (4)	21 Oct 2020 14:14:50

US3832150

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '0'	Alyssa-Kay Peay (b) (4)	21 Oct 2020 14:14:50

US3832150

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:04:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	21 Oct 2020 14:14:50

US3832150

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:04:59

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered empty.	Alyssa-Kay Peay (b) (4)	21 Oct 2020 14:14:50

US3832150

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:04:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '0'	Alyssa-Kay Peay (b) (4)	21 Oct 2020 14:14:50

US3832150

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:04:59

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered 'Jan 2008'	System	21 Oct 2020 14:14:50

US3832150

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:04:59

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered '2008'	System	21 Oct 2020 14:14:50

US3832150

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:04:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered empty.	System	21 Oct 2020 14:14:50

US3832150

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:04:59

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered empty.	System	21 Oct 2020 14:14:50

US3832150

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:04:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Colitis (excl infective), PT: Colitis, LLT: Colitis - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 16:15:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 16:15:46
Data point term sent to Coder	System	13 Nov 2020 16:15:01
User entered 'COLITIS'	Danyel Johnson (b) (4)	13 Nov 2020 16:14:26

US3832150

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:04:59

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'UN UNK 2018'	Danyel Johnson (b) (4)	13 Nov 2020 16:14:26

US3832150

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '0'	Danyel Johnson (b) (4)	13 Nov 2020 16:14:26

US3832150

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:04:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	13 Nov 2020 16:14:26

US3832150

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:04:59

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered empty.	Danyel Johnson (b) (4)	13 Nov 2020 16:14:26

US3832150

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:04:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '0'	Danyel Johnson (b) (4)	13 Nov 2020 16:14:26

US3832150

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:04:59

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered 'Jan 2018'	System	13 Nov 2020 16:14:26

US3832150

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:04:59

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered '2018'	System	13 Nov 2020 16:14:26

US3832150

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:04:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered empty.	System	13 Nov 2020 16:14:26

US3832150

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:04:59

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered empty.	System	13 Nov 2020 16:14:26

US3832150

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:04:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 18:48:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 18:48:01
Data point term sent to Coder	System	17 Feb 2021 18:39:02
User entered 'Seasonal Allergic Rhinitis'	Danyel Johnson (b) (4)	17 Feb 2021 18:38:10

US3832150

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:04:59

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'UN UNK 2018'	Danyel Johnson (b) (4)	17 Feb 2021 18:38:10

US3832150

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '0'	Danyel Johnson (b) (4)	17 Feb 2021 18:38:10

US3832150

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:04:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Yes (Y)'	(b) (4) Danyel Johnson (b) (4)	17 Feb 2021 18:38:10

US3832150

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:04:59

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered empty.	Danyel Johnson (b) (4)	17 Feb 2021 18:38:10

US3832150

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:04:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '0'	Danyel Johnson (b) (4)	17 Feb 2021 18:38:10

US3832150

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:04:59

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered 'Jan 2018'	System	17 Feb 2021 18:38:10

US3832150

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:04:59

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered '2018'	System	17 Feb 2021 18:38:10

US3832150

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:04:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered empty.	System	17 Feb 2021 18:38:10

US3832150

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:04:59

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered empty.	System	17 Feb 2021 18:38:10

US3832150

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:04:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac valve therapeutic procedures, PT: Aortic valve replacement, LLT: Aortic valve replacement - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	20 Apr 2021 19:52:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 19:52:32
Data point term sent to Coder	System	20 Apr 2021 19:51:46
User entered 'Aortic Valve Replacement'	Danyel Johnson (b) (4)	20 Apr 2021 19:50:50
	(b) (4)	

US3832150

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:04:59

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User entered 'un UNK 2012'	Danyel Johnson (b) (4)	20 Apr 2021 19:50:50

US3832150

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User entered '0'	Danyel Johnson (b) (4)	20 Apr 2021 19:50:50

US3832150

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:04:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User entered 'No (N)'	Danyel Johnson (b) (4)	20 Apr 2021 19:50:50

US3832150

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:04:59

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User entered 'un UNK 2012'	Danyel Johnson (b) (4)	20 Apr 2021 19:50:50

US3832150

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:04:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User entered '0'	Danyel Johnson (b) (4)	20 Apr 2021 19:50:50

US3832150

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:04:59

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered 'Jan 2012'	System	20 Apr 2021 19:50:50

US3832150

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:04:59

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered '2012'	System	20 Apr 2021 19:50:50

US3832150

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:04:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered 'Jan 2012'	System	20 Apr 2021 19:50:50

US3832150

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:04:59

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered '2012'	System	20 Apr 2021 19:50:50

US3832150

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:04:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Ovarian therapeutic procedures, PT: Oophorectomy, LLT: Oophorectomy - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 19:52:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 19:52:32
Data point term sent to Coder	System	20 Apr 2021 19:51:46
User entered 'Oophorectomy'	Danyel Johnson (b) (4)	20 Apr 2021 19:51:32

US3832150

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:04:59

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User entered 'un UNK 1987'	Danyel Johnson (b) (4)	20 Apr 2021 19:51:32

US3832150

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User entered '0'	Danyel Johnson (b) (4)	20 Apr 2021 19:51:32

US3832150

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:04:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User entered 'No (N)'	Danyel Johnson (b) (4)	20 Apr 2021 19:51:32

US3832150

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:04:59

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User entered 'un UNK 1987'	Danyel Johnson (b) (4)	20 Apr 2021 19:51:32

US3832150

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:04:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User entered '0'	Danyel Johnson (b) (4)	20 Apr 2021 19:51:32

US3832150

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:04:59

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered 'Jan 1987'	System	20 Apr 2021 19:51:32

US3832150

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:04:59

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered '1987'	System	20 Apr 2021 19:51:32

US3832150

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:04:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered 'Jan 1987'	System	20 Apr 2021 19:51:32

US3832150

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:04:59

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered '1987'	System	20 Apr 2021 19:51:32

US3832150

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:04:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendectomy, LLT: Appendectomy - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 19:53:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 19:53:35
Data point term sent to Coder	System	20 Apr 2021 19:52:46
User entered 'Appendectomy'	Danyel Johnson (b) (4)	20 Apr 2021 19:52:21

US3832150

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:04:59

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User entered 'un UNK 1987'	Danyel Johnson (b) (4)	20 Apr 2021 19:52:21

US3832150

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User entered '0'	Danyel Johnson (b) (4)	20 Apr 2021 19:52:21

US3832150

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:04:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User entered 'No (N)'	Danyel Johnson (b) (4)	20 Apr 2021 19:52:21

US3832150

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:04:59

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User entered 'un UNK 1987'	Danyel Johnson (b) (4)	20 Apr 2021 19:52:21

US3832150

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:04:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User entered '0'	Danyel Johnson (b) (4)	20 Apr 2021 19:52:21

US3832150

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:04:59

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered 'Jan 1987'	System	20 Apr 2021 19:52:21

US3832150

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:04:59

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered '1987'	System	20 Apr 2021 19:52:21

US3832150

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:04:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered 'Jan 1987'	System	20 Apr 2021 19:52:21

US3832150

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:04:59

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered '1987'	System	20 Apr 2021 19:52:21

US3832150

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:04:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Appendicitis - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 19:55:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 19:55:40
Data point term sent to Coder	System	20 Apr 2021 19:54:48
User entered 'Appendicitis'	Danyel Johnson (b) (4)	20 Apr 2021 19:54:03

US3832150

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:04:59

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User entered 'un UNK 1987'	Danyel Johnson (b) (4)	20 Apr 2021 19:54:03

US3832150

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User entered '0'	Danyel Johnson (b) (4)	20 Apr 2021 19:54:03

US3832150

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:04:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User entered 'No (N)'	Danyel Johnson (b) (4)	20 Apr 2021 19:54:03

US3832150

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:04:59

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User entered 'un UNK 1987'	Danyel Johnson (b) (4)	20 Apr 2021 19:54:03

US3832150

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:04:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User entered '0'	Danyel Johnson (b) (4)	20 Apr 2021 19:54:03

US3832150

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:04:59

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered 'Jan 1987'	System	20 Apr 2021 19:54:03

US3832150

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:04:59

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered '1987'	System	20 Apr 2021 19:54:03

US3832150

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:04:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered 'Jan 1987'	System	20 Apr 2021 19:54:03

US3832150

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:04:59

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered '1987'	System	20 Apr 2021 19:54:03

US3832150

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:15:30

US3832150

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '10 Aug 2020'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:15:30

US3832150

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '15:58'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:15:30

US3832150

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered '10 Aug 2020 15:58'	System	10 Aug 2020 20:15:30

US3832150

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '163.8' cm	(b) (4) Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:15:30
DataPoint set to visible.	(b) (4) System	10 Aug 2020 20:12:20

US3832150

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '58.1' kg	(b) (4) Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:15:30
DataPoint set to visible.	(b) (4) System	10 Aug 2020 20:12:20

US3832150

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
Amendment Manager: User entered '21.65451'	System	16 Sep 2020 23:50:34
User entered '21.7'	System	10 Aug 2020 20:15:30
DataPoint set to visible.	System	10 Aug 2020 20:12:20

US3832150

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered 'kg/m2'	System	10 Aug 2020 20:15:30
DataPoint set to visible.	System	10 Aug 2020 20:12:20

US3832150

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '98.8' F	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:15:30

US3832150

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Oral (Oral)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:15:30

US3832150

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered empty.	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:15:30

US3832150

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '69'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:15:30

US3832150

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered 'bpm'	System	10 Aug 2020 20:15:30

US3832150

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '18'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:15:30

US3832150

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered 'breaths/min'	System	10 Aug 2020 20:15:30

US3832150

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '110'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:15:30

US3832150

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered 'mmHg'	System	10 Aug 2020 20:15:30

US3832150

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '65'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:15:30

US3832150

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User entered 'mmHg'	System	10 Aug 2020 20:15:30

US3832150

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04

US3832150

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04

US3832150

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:04:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:15:39

US3832150

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:04:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Sep 2020 18:49:49
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	09 Sep 2020 22:28:57
User entered '10 Aug 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	10 Aug 2020 20:15:39

US3832150

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:04:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered '10 Aug 2020'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:16:40

US3832150

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:04:59

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:16:40

US3832150

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:04:59

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 10:10:42
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' answered with 'Verified and updated' (Site from DM).	Alyssa-Kay Peay (b) (4) (b) (4)	21 Oct 2020 14:15:22
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 07:11:22
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	10 Aug 2020 20:16:40

US3832150

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:04:59

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered empty.	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:16:40

US3832150

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:04:59

If Surgically sterile, date of surgery (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered empty.	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:16:40

US3832150

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:04:59

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered '0'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:16:40

US3832150

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:04:59

If Post-menopausal, date of last menstruation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered 'UN UNK 2008' reason for change:	(b) (4)	
Data Entry Error	Alyssa-Kay Peay (b) (4)	21 Oct 2020 14:15:11
User entered empty.	(b) (4)	
	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:16:40
	(b) (4)	

US3832150

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:04:59

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Alyssa-Kay Peay (b) (4)	21 Oct 2020 14:15:11
User entered '1'	(b) (4)	
	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:16:40
	(b) (4)	

US3832150

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:59

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'No (N)'	(b) (4) Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:17:35

US3832150

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:59

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'No (N)'	(b) (4) Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:17:35

US3832150

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:59

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:17:35

US3832150

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:59

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:17:35

US3832150

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:59

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'No (N)'	(b) (4) Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:17:35

US3832150

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:59

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:17:35

US3832150

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:59

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:17:35

US3832150

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:59

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:17:35

US3832150

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:59

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'No (N)'	(b) (4) Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:17:35

US3832150

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:59

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:17:35

US3832150

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:59

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:17:35

US3832150

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:59

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:17:35

US3832150

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:59

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered empty.	(b) (4) Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:17:35

US3832150

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:59

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '0'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:17:35

US3832150

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:59

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '0'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:17:35

US3832150

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:59

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '0'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:17:35

US3832150

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:59

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '0'	(b) (4) Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:17:35

US3832150

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:59

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '0'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:17:35

US3832150

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:59

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '0'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:17:35

US3832150

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:59

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'I'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:17:35

US3832150

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:59

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:04
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Participant attended large group events in the past few weeks (e.g., wedding, places of worship, concert)'	(b) (4) Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:17:35

US3832150

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:04:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:17:46

US3832150

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:04:59

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '10 Aug 2020'	(b) (4) Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:17:46

US3832150

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:04:59

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Clinic (Clinic)'	(b) (4) Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:17:46

US3832150

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:04:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered 'VISIT1'	System	10 Aug 2020 20:17:46

US3832150

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:04:59

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '10 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 20:09:35

US3832150

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:04:59

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 03:24:06
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:24:05
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Aug 2020 20:09:35
User entered '143573' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 20:09:35

US3832150

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:04:59

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 20:09:35

US3832150

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:04:59

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)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:18:20

US3832150

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:04:59

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)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:18:20

US3832150

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:04:59

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'No (N)'	(b) (4) Alyssa-Kay Peay (b) (4) (b) (4)	10 Aug 2020 20:18:20

US3832150

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:04:59

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'No (N)'	(b) (4) Alyssa-Kay Peay (b) (4) (b) (4)	10 Aug 2020 20:18:20

US3832150

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:04:59

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:18:20

US3832150

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:04:59

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User closed query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at HEUGHT and WEIGHT at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:20:14
Query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at HEUGHT and WEIGHT at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' answered with 'updated ' (Site from DM).	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 21:20:57
User entered missing code ND - Not Done; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 21:20:50
User opened query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at HEUGHT and WEIGHT at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 13:23:00
User entered '163.8' cm	Ashten Sheriff (b) (4) (b) (4)	10 Aug 2020 21:18:38

US3832150

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:04:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	10 Nov 2020 21:20:50
User entered '58.1' kg	Ashlen Sheriff (b) (4)	10 Aug 2020 21:18:38
	(b) (4)	

US3832150

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:04:59

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User closed query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at HEUGHT and WEIGHT at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:20:14
Query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at HEUGHT and WEIGHT at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' answered with 'updated ' (Site from DM).	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 21:20:57
User entered missing code ND - Not Done; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 21:20:50
User opened query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at HEUGHT and WEIGHT at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 13:23:00
User entered '163.8' cm	Ashten Sheriff (b) (4) (b) (4)	10 Aug 2020 21:18:38

US3832150

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:04:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	10 Nov 2020 21:20:50
User entered '58.1' kg	Ashlen Sheriff (b) (4)	10 Aug 2020 21:18:38
	(b) (4)	

US3832150

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User accepted default value 'Pre-Dose (PREDOSE)'	Ashten Sheriff (b) (4) (b) (4)	10 Aug 2020 21:18:38

US3832150

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	10 Aug 2020 21:18:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '10 Aug 2020'	Ashten Sheriff (b) (4)	10 Aug 2020 21:18:38

US3832150

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '15:58'	Ashten Sheriff (b) (4)	10 Aug 2020 21:18:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered '10 Aug 2020 15:58'	System	10 Aug 2020 21:18:38

US3832150

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '98.8' F reason for change: Data Entry Error	(b) (4)	
	Ashten Sheriff (b) (4)	10 Aug 2020 21:20:32
User entered '98.9' F	(b) (4)	
	Ashten Sheriff (b) (4)	10 Aug 2020 21:18:38
	(b) (4)	

US3832150

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Oral (Oral)'	Ashten Sheriff (b) (4)	10 Aug 2020 21:18:38

US3832150

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered empty.	(b) (4) Ashten Sheriff (b) (4)	10 Aug 2020 21:18:38

US3832150

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '69'	Ashten Sheriff (b) (4)	10 Aug 2020 21:18:38

US3832150

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered 'bpm'	System	10 Aug 2020 21:18:38

US3832150

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '18'	Ashten Sheriff (b) (4)	10 Aug 2020 21:18:38

US3832150

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered 'breaths/min'	System	10 Aug 2020 21:18:38

US3832150

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '110'	Ashten Sheriff (b) (4)	10 Aug 2020 21:18:38

US3832150

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered 'mmHg'	System	10 Aug 2020 21:18:38

US3832150

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '65'	Ashten Sheriff (b) (4)	10 Aug 2020 21:18:38

US3832150

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered 'mmHg'	System	10 Aug 2020 21:18:38

US3832150

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:04:59

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User closed query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at HEUGHT and WEIGHT at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:20:14
Query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at HEUGHT and WEIGHT at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' answered with 'updated ' (Site from DM).	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 21:20:57
User entered missing code ND - Not Done; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 21:20:50
User opened query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at HEUGHT and WEIGHT at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 13:23:00
User entered '163.8' cm	Ashten Sheriff (b) (4) (b) (4)	10 Aug 2020 21:18:38

US3832150

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:04:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	10 Nov 2020 21:20:50
User entered '58.1' kg	Ashen Sheriff (b) (4)	10 Aug 2020 21:18:38
	(b) (4)	

US3832150

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User accepted default value 'Post-Dose (POSTDOSE)'	Ashten Sheriff (b) (4) (b) (4)	10 Aug 2020 21:18:38

US3832150

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Yes (Y)'	(b) (4) Ashten Sheriff (b) (4)	10 Aug 2020 21:18:38

US3832150

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '10 Aug 2020'	Ashten Sheriff (b) (4)	10 Aug 2020 21:18:38

US3832150

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User closed query 'Per CDM Re-Query: Site response noted; however per protocol post-dose Vital Signs are to be collected 30 min after exposure. However, they were collected 26 min after exposure. Please clarify the post-dosing time of assessment and update as needed. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:20:27
Query 'Per CDM Re-Query: Site response noted; however per protocol post-dose Vital Signs are to be collected 30 min after exposure. However, they were collected 26 min after exposure. Please clarify the post-dosing time of assessment and update as needed. Thank you.' answered with 'data is correct as entered. PD to be noted ' (Site from DM).	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 21:28:45
User opened query 'Per CDM Re-Query: Site response noted; however per protocol post-dose Vital Signs are to be collected 30 min after exposure. However, they were collected 26 min after exposure. Please clarify the post-dosing time of assessment and update as needed. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 13:24:58
User closed query 'Per CDM: the treatment time on the Exposure CRF is 16:39. The Vital Signs Post Dose Time of Assessment is 17:05. Per protocol the post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 13:24:58
Query 'Per CDM: the treatment time on the Exposure CRF is 16:39. The Vital Signs Post Dose Time of Assessment is 17:05. Per protocol the post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed.' answered with 'Non-Clinically Significant per PA' (Site from DM).	Alyssa-Kay Peay (b) (4) (b) (4)	26 Oct 2020 18:05:30
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 13:55:12

US3832150

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User opened query 'Per CDM: the treatment time on the Exposure CRF is 16:39. The Vital Signs Post Dose Time of Assessment is 17:05. Per protocol the post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed.' (Site from DM). Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 min per protocol' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 13:55:09
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	Ashten Sheriff (b) (4)	10 Aug 2020 21:18:56
User entered '17:05'	(b) (4)	
	Ashten Sheriff (b) (4)	10 Aug 2020 21:18:38
	(b) (4)	

US3832150

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered '10 Aug 2020 17:05'	System	10 Aug 2020 21:18:38

US3832150

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '97.8' F	Ashten Sheriff (b) (4)	10 Aug 2020 21:18:38

US3832150

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Oral (Oral)'	(b) (4) Ashten Sheriff (b) (4)	10 Aug 2020 21:18:38

US3832150

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered empty.	Ashten Sheriff (b) (4)	10 Aug 2020 21:18:38

US3832150

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '61'	Ashten Sheriff (b) (4)	10 Aug 2020 21:18:38

US3832150

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered 'bpm'	System	10 Aug 2020 21:18:38

US3832150

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '16'	Ashten Sheriff (b) (4)	10 Aug 2020 21:18:38

US3832150

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered 'breaths/min'	System	10 Aug 2020 21:18:38

US3832150

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '126'	Ashten Sheriff (b) (4)	10 Aug 2020 21:18:38

US3832150

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered 'mmHg'	System	10 Aug 2020 21:18:38

US3832150

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '73'	Ashten Sheriff (b) (4)	10 Aug 2020 21:18:38

US3832150

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered 'mmHg'	System	10 Aug 2020 21:18:38

US3832150

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:04:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:19:01

US3832150

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:04:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '10 Aug 2020'	(b) (4) Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:19:01

US3832150

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:04:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:43:57

US3832150

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:04:59

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered empty.	(b) (4) Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:43:57

US3832150

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:04:59

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)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered empty.	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:43:57

US3832150

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:04:59

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered 'MRNA-1273 OR PLACEBO'	System	10 Aug 2020 20:43:57

US3832150

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:04:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '10 Aug 2020'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:43:57

US3832150

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:04:59

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '16:39'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:43:57

US3832150

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:04:59

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered '10 Aug 2020 16:39'	System	10 Aug 2020 20:43:57

US3832150

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:04:59

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Left Arm (LEFT ARM)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:43:57

US3832150

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:04:59

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered 'ONCE'	System	10 Aug 2020 20:43:57

US3832150

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:04:59

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered 'INTRAMUSCULAR'	System	10 Aug 2020 20:43:57

US3832150

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:19:34

US3832150

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '10 Aug 2020'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:19:34

US3832150

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:59

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '16:12'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:19:34

US3832150

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered '10 Aug 2020 16:12'	System	10 Aug 2020 20:19:34

US3832150

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:04:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '10 Aug 2020'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:19:21

US3832150

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:04:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Alyssa-Kay Peay (b) (4) (b) (4)	10 Aug 2020 20:19:21

US3832150

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:04:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:19:21

US3832150

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:04:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '16:10'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:19:21

US3832150

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:04:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered '10 Aug 2020 16:10'	System	10 Aug 2020 20:19:21

US3832150

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:04:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Alyssa-Kay Peay (b) (4) (b) (4)	10 Aug 2020 20:19:21

US3832150

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:04:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Alyssa-Kay Peay (b) (4)	11 Nov 2020 16:50:34
User entered 'Yes (Y)'	(b) (4)	
	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:19:21
	(b) (4)	

US3832150

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:04:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4)	11 Nov 2020 16:50:34
User entered '16:10'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:19:21

US3832150

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:04:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered empty.	System	11 Nov 2020 16:50:34
User entered '10 Aug 2020 16:10'	System	10 Aug 2020 20:19:21

US3832150

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:04:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:19:38

US3832150

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:04:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered 'I'	System	10 Aug 2020 20:19:38

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	10 Aug 2020 20:43:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-10T17:10:31', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '3a58432a-8186-4474-98de-aa474620d4d5' User entered 'Yes (Y)'	System	10 Aug 2020 21:10:58
	System	10 Aug 2020 21:10:58

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-10T17:10:41', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '3a58432a-8186-4474-98de-aa474620d4d5' User entered '97.8'	System	10 Aug 2020 21:10:58
	System	10 Aug 2020 21:10:58

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-10T17:10:47', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '3a58432a-8186-4474-98de-aa474620d4d5'	System	10 Aug 2020 21:10:58
User entered 'No (N)'	System	10 Aug 2020 21:10:58

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-10T17:10:56', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '3a58432a-8186-4474-98de-aa474620d4d5'	System	10 Aug 2020 21:10:58
User entered '10 Aug 2020 17:10'	System	10 Aug 2020 21:10:58

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '10 Aug 2020 16:59'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '10 Aug 2020 19:29'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	10 Aug 2020 20:43:57
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-10T21:37:06', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'c4c1f157-0e50-4f62-8a22-7ffcde0fbdc3'	System	11 Aug 2020 01:40:16
User entered 'Yes (Y)'	System	11 Aug 2020 01:40:16

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-10T21:39:58', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'c4c1f157-0e50-4f62-8a22-7ffcde0fbdc3'	System	11 Aug 2020 01:40:16
User entered '97.6'	System	11 Aug 2020 01:40:16

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-10T21:40:05', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'c4c1f157-0e50-4f62-8a22-7ffcde0fbdc3'	System	11 Aug 2020 01:40:16
User entered 'No (N)'	System	11 Aug 2020 01:40:16

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-10T21:40:14', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'c4c1f157-0e50-4f62-8a22-7ffcde0fbdc3'	System	11 Aug 2020 01:40:16
User entered '10 Aug 2020 21:40'	System	11 Aug 2020 01:40:16

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '10 Aug 2020 20:24'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	10 Aug 2020 20:43:57
User entered 'Day 2'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:04:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-11T15:23:40', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'a6af2541-3dde-4236-89b2-897070993fe5' User entered 'Yes (Y)'	System	11 Aug 2020 19:25:37
	System	11 Aug 2020 19:25:37

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:04:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-11T15:25:23', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'a6af2541-3dde-4236-89b2-897070993fe5' User entered '97.7'	System	11 Aug 2020 19:25:37
	System	11 Aug 2020 19:25:37

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:04:59

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-11T15:25:27', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'a6af2541-3dde-4236-89b2-897070993fe5'	System	11 Aug 2020 19:25:37
User entered 'No (N)'	System	11 Aug 2020 19:25:37

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-11T15:25:33', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'a6af2541-3dde-4236-89b2-897070993fe5'	System	11 Aug 2020 19:25:37
User entered '11 Aug 2020 15:25'	System	11 Aug 2020 19:25:37

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	10 Aug 2020 20:43:57
User entered 'Day 3'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:04:59

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-12T15:04:41', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '2c581e60-2f91-4a6e-8685-1ea46587be5a' User entered 'Yes (Y)'	System	12 Aug 2020 19:05:11
	System	12 Aug 2020 19:05:11

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:04:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-12T15:04:56', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '2c581e60-2f91-4a6e-8685-1ea46587be5a' User entered '99.0'	System	12 Aug 2020 19:05:11
	System	12 Aug 2020 19:05:11

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:04:59

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-12T15:05:01', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '2c581e60-2f91-4a6e-8685-1ea46587be5a' User entered 'No (N)'	System	12 Aug 2020 19:05:11
	System	12 Aug 2020 19:05:11

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-12T15:05:07', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '2c581e60-2f91-4a6e-8685-1ea46587be5a' User entered '12 Aug 2020 15:05'	System	12 Aug 2020 19:05:11
	System	12 Aug 2020 19:05:11

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	10 Aug 2020 20:43:57
User entered 'Day 4'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:04:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-13T13:37:44', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'a3957f23-3142-4a25-8b49-51f6236a5d77'	System	13 Aug 2020 17:38:04
User entered 'Yes (Y)'	System	13 Aug 2020 17:38:04

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:04:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-13T13:37:50', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'a3957f23-3142-4a25-8b49-51f6236a5d77' User entered '97.3'	System	13 Aug 2020 17:38:04
	System	13 Aug 2020 17:38:04

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:04:59

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-13T13:37:56', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'a3957f23-3142-4a25-8b49-51f6236a5d77'	System	13 Aug 2020 17:38:04
User entered 'No (N)'	System	13 Aug 2020 17:38:04

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-13T13:38:00', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'a3957f23-3142-4a25-8b49-51f6236a5d77'	System	13 Aug 2020 17:38:04
User entered '13 Aug 2020 13:38'	System	13 Aug 2020 17:38:04

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	10 Aug 2020 20:43:57
User entered 'Day 5'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:04:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-14T20:59:46', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'ec319eb4-f3e5-4a62-86b2-493634773548' User entered 'Yes (Y)'	System	15 Aug 2020 01:00:16
	System	15 Aug 2020 01:00:16

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:04:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-14T20:59:57', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'ec319eb4-f3e5-4a62-86b2-493634773548' User entered '96.5'	System	15 Aug 2020 01:00:16
	System	15 Aug 2020 01:00:16

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:04:59

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-14T21:00:03', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'ec319eb4-f3e5-4a62-86b2-493634773548'	System	15 Aug 2020 01:00:16
User entered 'No (N)'	System	15 Aug 2020 01:00:16

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-14T21:00:13', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'ec319eb4-f3e5-4a62-86b2-493634773548'	System	15 Aug 2020 01:00:16
User entered '14 Aug 2020 21:00'	System	15 Aug 2020 01:00:16

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	10 Aug 2020 20:43:57
User entered 'Day 6'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:04:59

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-15T21:02:33', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'c045be20-48bc-4d89-b5cb-6fa2481ee1a1' User entered 'Yes (Y)'	System	16 Aug 2020 01:02:52
	System	16 Aug 2020 01:02:52

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:04:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-15T21:02:40', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'c045be20-48bc-4d89-b5cb-6fa2481ee1a1' User entered '98.3'	System	16 Aug 2020 01:02:52
	System	16 Aug 2020 01:02:52

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:04:59

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-15T21:02:45', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'c045be20-48bc-4d89-b5cb-6fa2481ee1a1' User entered 'No (N)'	System	16 Aug 2020 01:02:52
	System	16 Aug 2020 01:02:52

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-15T21:02:49', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'c045be20-48bc-4d89-b5cb-6fa2481ee1a1' User entered '15 Aug 2020 21:02'	System	16 Aug 2020 01:02:52
	System	16 Aug 2020 01:02:52

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	10 Aug 2020 20:43:57
User entered 'Day 7'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:04:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-16T19:46:26', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '5d68043a-774d-4630-a825-6bd1abda7954' User entered 'Yes (Y)'	System	16 Aug 2020 23:46:46
	System	16 Aug 2020 23:46:46

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:04:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-16T19:46:33', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '5d68043a-774d-4630-a825-6bd1abda7954' User entered '97.8'	System	16 Aug 2020 23:46:46
	System	16 Aug 2020 23:46:46

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:04:59

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-16T19:46:36', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '5d68043a-774d-4630-a825-6bd1abda7954'	System	16 Aug 2020 23:46:46
User entered 'No (N)'	System	16 Aug 2020 23:46:46

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-16T19:46:41', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '5d68043a-774d-4630-a825-6bd1abda7954'	System	16 Aug 2020 23:46:46
User entered '16 Aug 2020 19:46'	System	16 Aug 2020 23:46:46

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	10 Aug 2020 20:43:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-10T17:11:15', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '9cd44e42-55c5-498c-acfb-d60149bedef7' User entered 'None (1)'	System	10 Aug 2020 21:11:50
	System	10 Aug 2020 21:11:50

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-10T17:11:24', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '9cd44e42-55c5-498c-acfb-d60149bedef7' User entered 'No (N)'	System	10 Aug 2020 21:11:50
	System	10 Aug 2020 21:11:50

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-10T17:11:31', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '9cd44e42-55c5-498c-acfb-d60149bedef7' User entered 'No (N)'	System	10 Aug 2020 21:11:50
	System	10 Aug 2020 21:11:50

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-10T17:11:40', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '9cd44e42-55c5-498c-acfb-d60149bedef7' User entered 'None (1)'	System	10 Aug 2020 21:11:50
	System	10 Aug 2020 21:11:50

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-10T17:11:47', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '9cd44e42-55c5-498c-acfb-d60149bedef7' User entered '10 Aug 2020 17:11'	System	10 Aug 2020 21:11:50
	System	10 Aug 2020 21:11:50

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '10 Aug 2020 16:59'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '10 Aug 2020 19:29'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	10 Aug 2020 20:43:57
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-10T21:40:32', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '05725861-775f-4518-a0e7-6c80b6147bb8'	System	11 Aug 2020 01:41:03
User entered 'None (1)'	System	11 Aug 2020 01:41:03

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-10T21:40:41', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '05725861-775f-4518-a0e7-6c80b6147bb8'	System	11 Aug 2020 01:41:03
User entered 'No (N)'	System	11 Aug 2020 01:41:03

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-10T21:40:48', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '05725861-775f-4518-a0e7-6c80b6147bb8'	System	11 Aug 2020 01:41:03
User entered 'No (N)'	System	11 Aug 2020 01:41:03

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-10T21:40:56', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '05725861-775f-4518-a0e7-6c80b6147bb8'	System	11 Aug 2020 01:41:03
User entered 'None (1)'	System	11 Aug 2020 01:41:03

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-10T21:41:01', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '05725861-775f-4518-a0e7-6c80b6147bb8'	System	11 Aug 2020 01:41:03
User entered '10 Aug 2020 21:41'	System	11 Aug 2020 01:41:03

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '10 Aug 2020 20:24'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	10 Aug 2020 20:43:57
User entered 'Day 2'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:04:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-11T15:25:39', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '620e0efb-b0b4-4f14-ab27-390391618ec9' User entered 'None (1)'	System	11 Aug 2020 19:26:04
	System	11 Aug 2020 19:26:04

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:04:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-11T15:25:46', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '620e0efb-b0b4-4f14-ab27-390391618ec9' User entered 'No (N)'	System	11 Aug 2020 19:26:04
	System	11 Aug 2020 19:26:04

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:04:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-11T15:25:52', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '620e0efb-b0b4-4f14-ab27-390391618ec9' User entered 'No (N)'	System	11 Aug 2020 19:26:04
	System	11 Aug 2020 19:26:04

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:04:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-11T15:25:57', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '620e0efb-b0b4-4f14-ab27-390391618ec9' User entered 'None (1)'	System	11 Aug 2020 19:26:04
	System	11 Aug 2020 19:26:04

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-11T15:26:02', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '620e0efb-b0b4-4f14-ab27-390391618ec9' User entered '11 Aug 2020 15:26'	System	11 Aug 2020 19:26:04
	System	11 Aug 2020 19:26:04

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	10 Aug 2020 20:43:57
User entered 'Day 3'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:04:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-12T15:05:11', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '14815bab-2c83-46d9-9949-9ee50535b33b'	System	12 Aug 2020 19:06:49
User entered 'None (1)'	System	12 Aug 2020 19:06:49

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:04:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-12T15:06:30', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '14815bab-2c83-46d9-9949-9ee50535b33b' User entered 'No (N)'	System	12 Aug 2020 19:06:49
	System	12 Aug 2020 19:06:49

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:04:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-12T15:06:34', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '14815bab-2c83-46d9-9949-9ee50535b33b' User entered 'No (N)'	System	12 Aug 2020 19:06:49
	System	12 Aug 2020 19:06:49

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:04:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-12T15:06:39', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '14815bab-2c83-46d9-9949-9ee50535b33b'	System	12 Aug 2020 19:06:49
User entered 'None (1)'	System	12 Aug 2020 19:06:49

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-12T15:06:47', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '14815bab-2c83-46d9-9949-9ee50535b33b'	System	12 Aug 2020 19:06:49
User entered '12 Aug 2020 15:06'	System	12 Aug 2020 19:06:49

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	10 Aug 2020 20:43:57
User entered 'Day 4'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:04:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-13T13:38:17', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '59b911dd-37ef-43ea-aca3-640753effc55'	System	13 Aug 2020 17:38:37
User entered 'None (1)'	System	13 Aug 2020 17:38:37

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:04:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-13T13:38:20', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '59b911dd-37ef-43ea-aca3-640753effc55'	System	13 Aug 2020 17:38:37
User entered 'No (N)'	System	13 Aug 2020 17:38:37

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:04:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-13T13:38:26', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '59b911dd-37ef-43ea-aca3-640753effc55'	System	13 Aug 2020 17:38:37
User entered 'No (N)'	System	13 Aug 2020 17:38:37

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:04:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-13T13:38:30', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '59b911dd-37ef-43ea-aca3-640753effc55' User entered 'None (1)'	System	13 Aug 2020 17:38:37
	System	13 Aug 2020 17:38:37

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-13T13:38:34', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '59b911dd-37ef-43ea-aca3-640753effc55' User entered '13 Aug 2020 13:38'	System	13 Aug 2020 17:38:37
	System	13 Aug 2020 17:38:37

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	10 Aug 2020 20:43:57
User entered 'Day 5'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:04:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-14T21:00:19', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '3fed0568-4056-4a95-8245-f9c0ee133fd6'	System	15 Aug 2020 01:00:38
User entered 'None (1)'	System	15 Aug 2020 01:00:38

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:04:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-14T21:00:23', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '3fed0568-4056-4a95-8245-f9c0ee133fd6'	System	15 Aug 2020 01:00:38
User entered 'No (N)'	System	15 Aug 2020 01:00:38

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:04:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-14T21:00:26', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '3fed0568-4056-4a95-8245-f9c0ee133fd6'	System	15 Aug 2020 01:00:38
User entered 'No (N)'	System	15 Aug 2020 01:00:38

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:04:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-14T21:00:32', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '3fed0568-4056-4a95-8245-f9c0ee133fd6'	System	15 Aug 2020 01:00:38
User entered 'None (1)'	System	15 Aug 2020 01:00:38

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-14T21:00:35', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '3fed0568-4056-4a95-8245-f9c0ee133fd6'	System	15 Aug 2020 01:00:38
User entered '14 Aug 2020 21:00'	System	15 Aug 2020 01:00:38

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	10 Aug 2020 20:43:57
User entered 'Day 6'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:04:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-15T21:02:55', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '6f769b57-8201-4b68-9f33-13d463d7a830' User entered 'None (1)'	System	16 Aug 2020 01:03:13
	System	16 Aug 2020 01:03:13

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:04:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-15T21:02:58', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '6f769b57-8201-4b68-9f33-13d463d7a830' User entered 'No (N)'	System	16 Aug 2020 01:03:13
	System	16 Aug 2020 01:03:13

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:04:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-15T21:03:01', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '6f769b57-8201-4b68-9f33-13d463d7a830' User entered 'No (N)'	System	16 Aug 2020 01:03:13
	System	16 Aug 2020 01:03:13

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:04:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-15T21:03:05', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '6f769b57-8201-4b68-9f33-13d463d7a830'	System	16 Aug 2020 01:03:13
User entered 'None (1)'	System	16 Aug 2020 01:03:13

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-15T21:03:11', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '6f769b57-8201-4b68-9f33-13d463d7a830' User entered '15 Aug 2020 21:03'	System	16 Aug 2020 01:03:13
	System	16 Aug 2020 01:03:13

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	10 Aug 2020 20:43:57
User entered 'Day 7'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:04:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-16T19:46:47', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '40b626bc-14dd-45a6-ae15-c48a879e83f4' User entered 'None (1)'	System	16 Aug 2020 23:47:05
	System	16 Aug 2020 23:47:05

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:04:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-16T19:46:49', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '40b626bc-14dd-45a6-ae15-c48a879e83f4' User entered 'No (N)'	System	16 Aug 2020 23:47:05
	System	16 Aug 2020 23:47:05

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:04:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-16T19:46:52', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '40b626bc-14dd-45a6-ae15-c48a879e83f4' User entered 'No (N)'	System	16 Aug 2020 23:47:05
	System	16 Aug 2020 23:47:05

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:04:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-16T19:46:56', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '40b626bc-14dd-45a6-ae15-c48a879e83f4' User entered 'None (1)'	System	16 Aug 2020 23:47:05
	System	16 Aug 2020 23:47:05

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-16T19:47:02', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '40b626bc-14dd-45a6-ae15-c48a879e83f4' User entered '16 Aug 2020 19:47'	System	16 Aug 2020 23:47:05
	System	16 Aug 2020 23:47:05

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	10 Aug 2020 20:43:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-10T17:11:53', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '8c1494df-4977-4f6c-aecb-8c6edb091dbf' User entered 'None (0)'	System	10 Aug 2020 21:12:29
	System	10 Aug 2020 21:12:29

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-10T17:11:57', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '8c1494df-4977-4f6c-aecb-8c6edb091dbf' User entered 'None (0)'	System	10 Aug 2020 21:12:29
	System	10 Aug 2020 21:12:29

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-10T17:12:00', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '8c1494df-4977-4f6c-aecb-8c6edb091dbf' User entered 'None (0)'	System	10 Aug 2020 21:12:29
	System	10 Aug 2020 21:12:29

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-10T17:12:04', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '8c1494df-4977-4f6c-aecb-8c6edb091dbf' User entered 'None (0)'	System	10 Aug 2020 21:12:29
	System	10 Aug 2020 21:12:29

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-10T17:12:08', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '8c1494df-4977-4f6c-aecb-8c6edb091dbf' User entered 'None (0)'	System	10 Aug 2020 21:12:29
	System	10 Aug 2020 21:12:29

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-10T17:12:14', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '8c1494df-4977-4f6c-aecb-8c6edb091dbf' User entered 'None (0)'	System	10 Aug 2020 21:12:29
	System	10 Aug 2020 21:12:29

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-10T17:12:21', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '8c1494df-4977-4f6c-aecb-8c6edb091dbf' User entered 'No (N)'	System	10 Aug 2020 21:12:29
	System	10 Aug 2020 21:12:29

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-10T17:12:27', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '8c1494df-4977-4f6c-aecb-8c6edb091dbf' User entered '10 Aug 2020 17:12'	System	10 Aug 2020 21:12:29
	System	10 Aug 2020 21:12:29

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '10 Aug 2020 16:59'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '10 Aug 2020 19:29'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	10 Aug 2020 20:43:57
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-10T21:41:08', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '1721d0a1-a9f4-489d-8b02-45e6d91a8e31' User entered 'None (0)'	System	11 Aug 2020 01:41:43
	System	11 Aug 2020 01:41:43

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-10T21:41:14', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '1721d0a1-a9f4-489d-8b02-45e6d91a8e31' User entered 'None (0)'	System	11 Aug 2020 01:41:43
	System	11 Aug 2020 01:41:43

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-10T21:41:17', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '1721d0a1-a9f4-489d-8b02-45e6d91a8e31' User entered 'None (0)'	System	11 Aug 2020 01:41:43
	System	11 Aug 2020 01:41:43

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-10T21:41:21', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '1721d0a1-a9f4-489d-8b02-45e6d91a8e31' User entered 'None (0)'	System	11 Aug 2020 01:41:43
	System	11 Aug 2020 01:41:43

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-10T21:41:27', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '1721d0a1-a9f4-489d-8b02-45e6d91a8e31' User entered 'None (0)'	System	11 Aug 2020 01:41:43
	System	11 Aug 2020 01:41:43

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-10T21:41:30', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '1721d0a1-a9f4-489d-8b02-45e6d91a8e31' User entered 'None (0)'	System	11 Aug 2020 01:41:43
	System	11 Aug 2020 01:41:43

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-10T21:41:35', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '1721d0a1-a9f4-489d-8b02-45e6d91a8e31' User entered 'No (N)'	System	11 Aug 2020 01:41:43
	System	11 Aug 2020 01:41:43

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-10T21:41:40', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '1721d0a1-a9f4-489d-8b02-45e6d91a8e31' User entered '10 Aug 2020 21:41'	System	11 Aug 2020 01:41:43
	System	11 Aug 2020 01:41:43

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '10 Aug 2020 20:24'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	10 Aug 2020 20:43:57
User entered 'Day 2'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-11T15:26:16', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'ac1b539a-70b4-46b2-bf57-746748a106fb' User entered 'None (0)'	System	11 Aug 2020 19:26:44
	System	11 Aug 2020 19:26:44

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-11T15:26:21', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'ac1b539a-70b4-46b2-bf57-746748a106fb' User entered 'None (0)'	System	11 Aug 2020 19:26:44
	System	11 Aug 2020 19:26:44

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-11T15:26:24', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'ac1b539a-70b4-46b2-bf57-746748a106fb' User entered 'None (0)'	System	11 Aug 2020 19:26:44
	System	11 Aug 2020 19:26:44

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-11T15:26:27', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'ac1b539a-70b4-46b2-bf57-746748a106fb' User entered 'None (0)'	System	11 Aug 2020 19:26:44
	System	11 Aug 2020 19:26:44

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-11T15:26:30', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'ac1b539a-70b4-46b2-bf57-746748a106fb' User entered 'None (0)'	System	11 Aug 2020 19:26:44
	System	11 Aug 2020 19:26:44

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-11T15:26:33', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'ac1b539a-70b4-46b2-bf57-746748a106fb' User entered 'None (0)'	System	11 Aug 2020 19:26:44
	System	11 Aug 2020 19:26:44

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-11T15:26:38', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'ac1b539a-70b4-46b2-bf57-746748a106fb' User entered 'No (N)'	System	11 Aug 2020 19:26:44
	System	11 Aug 2020 19:26:44

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-11T15:26:42', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'ac1b539a-70b4-46b2-bf57-746748a106fb' User entered '11 Aug 2020 15:26'	System	11 Aug 2020 19:26:44
	System	11 Aug 2020 19:26:44

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	10 Aug 2020 20:43:57
User entered 'Day 3'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-12T15:06:54', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '467a6274-9dac-4c29-9a4e-511d3440741a'	System	12 Aug 2020 19:08:19
User entered 'No interference with activity (1)'	System	12 Aug 2020 19:08:19

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-12T15:07:03', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '467a6274-9dac-4c29-9a4e-511d3440741a' User entered 'None (0)'	System	12 Aug 2020 19:08:19
	System	12 Aug 2020 19:08:19

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-12T15:07:09', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '467a6274-9dac-4c29-9a4e-511d3440741a' User entered 'None (0)'	System	12 Aug 2020 19:08:19
	System	12 Aug 2020 19:08:19

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-12T15:07:30', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '467a6274-9dac-4c29-9a4e-511d3440741a' User entered 'None (0)'	System	12 Aug 2020 19:08:19
	System	12 Aug 2020 19:08:19

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-12T15:07:54', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '467a6274-9dac-4c29-9a4e-511d3440741a'	System	12 Aug 2020 19:08:19
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	12 Aug 2020 19:08:19

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-12T15:07:57', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '467a6274-9dac-4c29-9a4e-511d3440741a' User entered 'None (0)'	System	12 Aug 2020 19:08:19
	System	12 Aug 2020 19:08:19

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-12T15:08:04', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '467a6274-9dac-4c29-9a4e-511d3440741a' User entered 'No (N)'	System	12 Aug 2020 19:08:19
	System	12 Aug 2020 19:08:19

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-12T15:08:17', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '467a6274-9dac-4c29-9a4e-511d3440741a' User entered '12 Aug 2020 15:08'	System	12 Aug 2020 19:08:19
	System	12 Aug 2020 19:08:19

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	10 Aug 2020 20:43:57
User entered 'Day 4'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-13T13:38:43', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '50b98ae7-47fe-4ccf-a41a-3ded7a333cf6' User entered 'None (0)'	System	13 Aug 2020 17:40:14
	System	13 Aug 2020 17:40:14

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-13T13:39:06', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '50b98ae7-47fe-4ccf-a41a-3ded7a333cf6' User entered 'None (0)'	System	13 Aug 2020 17:40:14
	System	13 Aug 2020 17:40:14

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-13T13:39:09', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '50b98ae7-47fe-4ccf-a41a-3ded7a333cf6' User entered 'None (0)'	System	13 Aug 2020 17:40:14
	System	13 Aug 2020 17:40:14

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-13T13:39:21', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '50b98ae7-47fe-4ccf-a41a-3ded7a333cf6' User entered 'None (0)'	System	13 Aug 2020 17:40:14
	System	13 Aug 2020 17:40:14

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-13T13:39:24', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '50b98ae7-47fe-4ccf-a41a-3ded7a333cf6' User entered 'None (0)'	System	13 Aug 2020 17:40:14
	System	13 Aug 2020 17:40:14

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-13T13:39:26', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '50b98ae7-47fe-4ccf-a41a-3ded7a333cf6' User entered 'None (0)'	System	13 Aug 2020 17:40:14
	System	13 Aug 2020 17:40:14

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-13T13:39:31', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '50b98ae7-47fe-4ccf-a41a-3ded7a333cf6'	System	13 Aug 2020 17:40:14
User entered 'No (N)'	System	13 Aug 2020 17:40:14

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-13T13:40:10', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '50b98ae7-47fe-4ccf-a41a-3ded7a333cf6' User entered '13 Aug 2020 13:40'	System	13 Aug 2020 17:40:14
	System	13 Aug 2020 17:40:14

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	10 Aug 2020 20:43:57
User entered 'Day 5'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-14T21:00:40', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '6a1557d6-059e-4d17-9f40-b0a8851b5e5c' User entered 'None (0)'	System	15 Aug 2020 01:01:12
	System	15 Aug 2020 01:01:12

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-14T21:00:43', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '6a1557d6-059e-4d17-9f40-b0a8851b5e5c' User entered 'None (0)'	System	15 Aug 2020 01:01:12
	System	15 Aug 2020 01:01:12

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-14T21:00:46', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '6a1557d6-059e-4d17-9f40-b0a8851b5e5c' User entered 'None (0)'	System	15 Aug 2020 01:01:12
	System	15 Aug 2020 01:01:12

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-14T21:00:49', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '6a1557d6-059e-4d17-9f40-b0a8851b5e5c' User entered 'None (0)'	System	15 Aug 2020 01:01:12
	System	15 Aug 2020 01:01:12

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-14T21:00:52', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '6a1557d6-059e-4d17-9f40-b0a8851b5e5c' User entered 'None (0)'	System	15 Aug 2020 01:01:12
	System	15 Aug 2020 01:01:12

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-14T21:00:56', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '6a1557d6-059e-4d17-9f40-b0a8851b5e5c' User entered 'None (0)'	System	15 Aug 2020 01:01:12
	System	15 Aug 2020 01:01:12

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-14T21:01:04', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '6a1557d6-059e-4d17-9f40-b0a8851b5e5c' User entered 'No (N)'	System	15 Aug 2020 01:01:12
	System	15 Aug 2020 01:01:12

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-14T21:01:09', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '6a1557d6-059e-4d17-9f40-b0a8851b5e5c' User entered '14 Aug 2020 21:01'	System	15 Aug 2020 01:01:12
	System	15 Aug 2020 01:01:12

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	10 Aug 2020 20:43:57
User entered 'Day 6'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-15T21:03:16', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '83caa395-22e3-4b09-9718-a52e3ebbc93f' User entered 'None (0)'	System	16 Aug 2020 01:03:50
	System	16 Aug 2020 01:03:50

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-15T21:03:21', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '83caa395-22e3-4b09-9718-a52e3ebbc93f' User entered 'None (0)'	System	16 Aug 2020 01:03:50
	System	16 Aug 2020 01:03:50

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-15T21:03:25', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '83caa395-22e3-4b09-9718-a52e3ebbc93f' User entered 'None (0)'	System	16 Aug 2020 01:03:50
	System	16 Aug 2020 01:03:50

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-15T21:03:29', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '83caa395-22e3-4b09-9718-a52e3ebbc93f' User entered 'None (0)'	System	16 Aug 2020 01:03:50
	System	16 Aug 2020 01:03:50

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-15T21:03:32', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '83caa395-22e3-4b09-9718-a52e3ebbc93f' User entered 'None (0)'	System	16 Aug 2020 01:03:50
	System	16 Aug 2020 01:03:50

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-15T21:03:35', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '83caa395-22e3-4b09-9718-a52e3ebbc93f' User entered 'None (0)'	System	16 Aug 2020 01:03:50
	System	16 Aug 2020 01:03:50

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-15T21:03:45', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '83caa395-22e3-4b09-9718-a52e3ebbc93f' User entered 'No (N)'	System	16 Aug 2020 01:03:50
	System	16 Aug 2020 01:03:50

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-15T21:03:48', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '83caa395-22e3-4b09-9718-a52e3ebbc93f' User entered '15 Aug 2020 21:03'	System	16 Aug 2020 01:03:50
	System	16 Aug 2020 01:03:50

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	10 Aug 2020 20:43:57
User entered 'Day 7'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-16T19:47:07', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '869c2f5f-01a2-4e3e-9f53-143f4f552608'	System	16 Aug 2020 23:47:54
User entered 'None (0)'	System	16 Aug 2020 23:47:54

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-16T19:47:10', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '869c2f5f-01a2-4e3e-9f53-143f4f552608' User entered 'None (0)'	System	16 Aug 2020 23:47:54
	System	16 Aug 2020 23:47:54

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-16T19:47:14', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '869c2f5f-01a2-4e3e-9f53-143f4f552608' User entered 'None (0)'	System	16 Aug 2020 23:47:54
	System	16 Aug 2020 23:47:54

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-16T19:47:30', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '869c2f5f-01a2-4e3e-9f53-143f4f552608' User entered 'None (0)'	System	16 Aug 2020 23:47:54
	System	16 Aug 2020 23:47:54

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-16T19:47:34', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '869c2f5f-01a2-4e3e-9f53-143f4f552608' User entered 'None (0)'	System	16 Aug 2020 23:47:54
	System	16 Aug 2020 23:47:54

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-16T19:47:37', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '869c2f5f-01a2-4e3e-9f53-143f4f552608'	System	16 Aug 2020 23:47:54
User entered 'None (0)'	System	16 Aug 2020 23:47:54

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-16T19:47:45', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '869c2f5f-01a2-4e3e-9f53-143f4f552608'	System	16 Aug 2020 23:47:54
User entered 'No (N)'	System	16 Aug 2020 23:47:54

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-08-16T19:47:49', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '869c2f5f-01a2-4e3e-9f53-143f4f552608' User entered '16 Aug 2020 19:47'	System	16 Aug 2020 23:47:54
	System	16 Aug 2020 23:47:54

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 20:43:57

US3832150

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 20:43:57

US3832150

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4) (b) (4)	17 Aug 2020 21:41:00

US3832150

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered '17 Aug 2020'	Alyssa-Kay Peay (b) (4)	17 Aug 2020 21:41:00

US3832150

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4)	17 Aug 2020 21:41:00

US3832150

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered empty.	Alyssa-Kay Peay (b) (4)	17 Aug 2020 21:41:00

US3832150

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	17 Aug 2020 21:41:08

US3832150

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:37
User entered 'I'	System	17 Aug 2020 21:41:08

US3832150

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:25:34

US3832150

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '24 Aug 2020'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:25:34

US3832150

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:25:34

US3832150

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered empty.	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:25:34

US3832150

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:25:37

US3832150

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:37
User entered 'I'	System	24 Aug 2020 19:25:37

US3832150

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	31 Aug 2020 19:50:59

US3832150

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '31 Aug 2020'	Ashten Sheriff (b) (4)	31 Aug 2020 19:50:59

US3832150

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Contact Made (CONTACT MADE)'	Ashten Sheriff (b) (4)	31 Aug 2020 19:50:59

US3832150

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered empty.	Ashten Sheriff (b) (4)	31 Aug 2020 19:50:59

US3832150

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	31 Aug 2020 19:51:10

US3832150

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:37
User entered 'I'	System	31 Aug 2020 19:51:10

US3832150

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Yes (Y)'	(b) (4)	09 Sep 2020 22:28:57
	(b) (4), (b) (6)	

US3832150

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:59

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '9 Sep 2020'	(b) (4)	09 Sep 2020 22:28:57
	(b) (4), (b) (6)	

US3832150

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:59

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 22:28:57

US3832150

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered 'VISIT2'	System	09 Sep 2020 22:28:57

US3832150

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	09 Sep 2020 22:30:58

US3832150

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Yes (Y)'	(b) (4)	09 Sep 2020 22:30:58
	(b) (4), (b) (6)	

US3832150

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '9 Sep 2020'	(b) (4)	09 Sep 2020 22:30:58
	(b) (4), (b) (6)	

US3832150

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '16:05'	(b) (4)	09 Sep 2020 22:30:58
	(b) (4), (b) (6)	

US3832150

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered '9 Sep 2020 16:05'	System	09 Sep 2020 22:30:58

US3832150

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '98.2' F	(b) (4), (b) (6)	09 Sep 2020 22:30:58

US3832150

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Oral (Oral)'	(b) (4)	09 Sep 2020 22:30:58
	(b) (4), (b) (6)	

US3832150

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered empty.	(b) (4)	09 Sep 2020 22:30:58
	(b) (4), (b) (6)	

US3832150

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '71'	(b) (4)	09 Sep 2020 22:30:58
	(b) (4), (b) (6)	

US3832150

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered 'bpm'	System	09 Sep 2020 22:30:58

US3832150

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '15'	(b) (4)	09 Sep 2020 22:30:58
	(b) (4), (b) (6)	

US3832150

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered 'breaths/min'	System	09 Sep 2020 22:30:58

US3832150

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '113'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 22:30:58

US3832150

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered 'mmHg'	System	09 Sep 2020 22:30:58

US3832150

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '71'	(b) (4)	09 Sep 2020 22:30:58
	(b) (4), (b) (6)	

US3832150

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered 'mmHg'	System	09 Sep 2020 22:30:58

US3832150

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	09 Sep 2020 22:30:58

US3832150

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Yes (Y)'	(b) (4)	09 Sep 2020 22:30:58
	(b) (4), (b) (6)	

US3832150

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '9 Sep 2020'	(b) (4)	09 Sep 2020 22:30:58
	(b) (4), (b) (6)	

US3832150

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '17:00'	(b) (4)	09 Sep 2020 22:30:58
	(b) (4), (b) (6)	

US3832150

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered '9 Sep 2020 17:00'	System	09 Sep 2020 22:30:58

US3832150

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '97.7' F	(b) (4), (b) (6)	09 Sep 2020 22:30:58

US3832150

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Oral (Oral)'	(b) (4)	09 Sep 2020 22:30:58
	(b) (4), (b) (6)	

US3832150

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered empty.	(b) (4)	09 Sep 2020 22:30:58
	(b) (4), (b) (6)	

US3832150

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '69'	(b) (4)	09 Sep 2020 22:30:58
	(b) (4), (b) (6)	

US3832150

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered 'bpm'	System	09 Sep 2020 22:30:58

US3832150

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '16'	(b) (4)	09 Sep 2020 22:30:58
	(b) (4), (b) (6)	

US3832150

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered 'breaths/min'	System	09 Sep 2020 22:30:58

US3832150

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '129'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 22:30:58

US3832150

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered 'mmHg'	System	09 Sep 2020 22:30:58

US3832150

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '87'	(b) (4)	09 Sep 2020 22:30:58
	(b) (4), (b) (6)	

US3832150

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered 'mmHg'	System	09 Sep 2020 22:30:58

US3832150

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:04:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Yes (Y)'	(b) (4)	09 Sep 2020 22:31:08
	(b) (4), (b) (6)	

US3832150

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:04:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '9 Sep 2020'	(b) (4)	09 Sep 2020 22:31:08
	(b) (4), (b) (6)	

US3832150

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Yes (Y)'	(b) (4)	09 Sep 2020 20:39:19
	(b) (4), (b) (6)	

US3832150

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:59

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered empty.	(b) (4)	09 Sep 2020 20:39:19
	(b) (4), (b) (6)	

US3832150

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:59

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)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 20:39:19

US3832150

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:59

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered 'MRNA-1273 OR PLACEBO'	System	09 Sep 2020 20:39:19

US3832150

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '9 Sep 2020'	(b) (4)	09 Sep 2020 20:39:19
	(b) (4), (b) (6)	

US3832150

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:59

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '16:30'	(b) (4)	09 Sep 2020 20:39:19
	(b) (4), (b) (6)	

US3832150

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:59

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered '9 Sep 2020 16:30'	System	09 Sep 2020 20:39:19

US3832150

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:59

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:39:19

US3832150

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:59

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered 'ONCE'	System	09 Sep 2020 20:39:19

US3832150

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:59

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered 'INTRAMUSCULAR'	System	09 Sep 2020 20:39:19

US3832150

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 22:31:29

US3832150

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '9 Sep 2020'	(b) (4)	09 Sep 2020 22:31:29
	(b) (4), (b) (6)	

US3832150

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '16:27'	(b) (4)	09 Sep 2020 22:31:29
	(b) (4), (b) (6)	

US3832150

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered '9 Sep 2020 16:27'	System	09 Sep 2020 22:31:29

US3832150

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:04:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '9 Sep 2020'	(b) (4)	09 Sep 2020 22:32:00
	(b) (4), (b) (6)	

US3832150

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:04:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	09 Sep 2020 22:32:00

US3832150

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:04:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 22:32:00

US3832150

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:04:59

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '16:19'	(b) (4), (b) (6)	09 Sep 2020 22:32:00

US3832150

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:04:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered '9 Sep 2020 16:19'	System	09 Sep 2020 22:32:00

US3832150

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:04:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	09 Sep 2020 22:32:00

US3832150

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:04:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Alyssa-Kay Peay (b) (4)	11 Nov 2020 16:50:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Sep 2020 22:32:00

US3832150

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:04:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered empty; reason for change Data Entry Error	(b) (4)	
	Alyssa-Kay Peay (b) (4)	11 Nov 2020 16:50:19
User entered '16:19'	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 22:32:00

US3832150

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:04:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered empty.	System	11 Nov 2020 16:50:19
User entered '9 Sep 2020 16:19'	System	09 Sep 2020 22:32:00

US3832150

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Yes (Y)'	(b) (4)	09 Sep 2020 22:35:37
	(b) (4), (b) (6)	

US3832150

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered 'I'	System	09 Sep 2020 22:35:37

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	09 Sep 2020 20:39:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-09T17:01:50', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '8f0d2c23-67e9-4ac9-8444-accb38b01882' User entered 'Yes (Y)'	System	09 Sep 2020 21:02:18
	System	09 Sep 2020 21:02:18

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-09T17:01:59', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '8f0d2c23-67e9-4ac9-8444-accb38b01882' User entered '97.7'	System	09 Sep 2020 21:02:18
	System	09 Sep 2020 21:02:18

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-09T17:02:03', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '8f0d2c23-67e9-4ac9-8444-accb38b01882' User entered 'No (N)'	System	09 Sep 2020 21:02:18
	System	09 Sep 2020 21:02:18

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-09T17:02:15', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '8f0d2c23-67e9-4ac9-8444-accb38b01882' User entered '09 Sep 2020 17:02'	System	09 Sep 2020 21:02:18
	System	09 Sep 2020 21:02:18

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '09 Sep 2020 16:50'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '09 Sep 2020 19:20'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	09 Sep 2020 20:39:19
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '09 Sep 2020 20:15'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	09 Sep 2020 20:39:19
User entered 'Day 2'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:04:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-10T21:03:44', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '2527c727-28c4-4daa-a34b-0049001ba1a8' User entered 'Yes (Y)'	System	11 Sep 2020 01:04:07
	System	11 Sep 2020 01:04:07

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:04:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-10T21:03:53', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '2527c727-28c4-4daa-a34b-0049001ba1a8' User entered '97.2'	System	11 Sep 2020 01:04:07
	System	11 Sep 2020 01:04:07

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:04:59

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-10T21:03:58', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '2527c727-28c4-4daa-a34b-0049001ba1a8' User entered 'No (N)'	System	11 Sep 2020 01:04:07
	System	11 Sep 2020 01:04:07

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-10T21:04:02', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '2527c727-28c4-4daa-a34b-0049001ba1a8' User entered '10 Sep 2020 21:04'	System	11 Sep 2020 01:04:07
	System	11 Sep 2020 01:04:07

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	09 Sep 2020 20:39:19
User entered 'Day 3'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:04:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-11T18:56:08', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '58e460b1-ac3c-4079-bda8-e480f484ab6e' User entered 'Yes (Y)'	System	11 Sep 2020 22:56:30
	System	11 Sep 2020 22:56:30

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:04:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-11T18:56:13', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '58e460b1-ac3c-4079-bda8-e480f484ab6e' User entered '97.6'	System	11 Sep 2020 22:56:30
	System	11 Sep 2020 22:56:30

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:04:59

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-11T18:56:17', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '58e460b1-ac3c-4079-bda8-e480f484ab6e' User entered 'No (N)'	System	11 Sep 2020 22:56:30
	System	11 Sep 2020 22:56:30

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-11T18:56:22', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '58e460b1-ac3c-4079-bda8-e480f484ab6e' User entered '11 Sep 2020 18:56'	System	11 Sep 2020 22:56:30
	System	11 Sep 2020 22:56:30

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	09 Sep 2020 20:39:19
User entered 'Day 4'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:04:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-12T21:48:59', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'f40f6609-94ad-4fe5-aaa1-2c50e801c843' User entered 'Yes (Y)'	System	13 Sep 2020 01:49:18
	System	13 Sep 2020 01:49:18

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:04:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-12T21:49:07', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'f40f6609-94ad-4fe5-aaa1-2c50e801c843' User entered '97.4'	System	13 Sep 2020 01:49:18
	System	13 Sep 2020 01:49:18

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:04:59

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-12T21:49:11', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'f40f6609-94ad-4fe5-aaa1-2c50e801c843'	System	13 Sep 2020 01:49:18
User entered 'No (N)'	System	13 Sep 2020 01:49:18

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-12T21:49:17', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'f40f6609-94ad-4fe5-aaa1-2c50e801c843'	System	13 Sep 2020 01:49:18
User entered '12 Sep 2020 21:49'	System	13 Sep 2020 01:49:18

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	09 Sep 2020 20:39:19
User entered 'Day 5'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:04:59

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-13T20:30:20', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '9c9b605a-283f-4a11-9b8a-5d49f3909ede' User entered 'Yes (Y)'	System	14 Sep 2020 00:31:37
	System	14 Sep 2020 00:31:37

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:04:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-13T20:31:26', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '9c9b605a-283f-4a11-9b8a-5d49f3909ede' User entered '97.6'	System	14 Sep 2020 00:31:37
	System	14 Sep 2020 00:31:37

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:04:59

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-13T20:31:30', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '9c9b605a-283f-4a11-9b8a-5d49f3909ede' User entered 'No (N)'	System	14 Sep 2020 00:31:37
	System	14 Sep 2020 00:31:37

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-13T20:31:34', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '9c9b605a-283f-4a11-9b8a-5d49f3909ede' User entered '13 Sep 2020 20:31'	System	14 Sep 2020 00:31:37
	System	14 Sep 2020 00:31:37

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	09 Sep 2020 20:39:19
User entered 'Day 6'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:04:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-14T21:00:19', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '182bd9d3-acb6-4cbf-bec1-87b6110725b1' User entered 'Yes (Y)'	System	15 Sep 2020 01:00:39
	System	15 Sep 2020 01:00:39

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:04:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-14T21:00:26', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '182bd9d3-acb6-4cbf-bec1-87b6110725b1' User entered '97.6'	System	15 Sep 2020 01:00:39
	System	15 Sep 2020 01:00:39

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:04:59

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-14T21:00:30', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '182bd9d3-acb6-4cbf-bec1-87b6110725b1' User entered 'No (N)'	System	15 Sep 2020 01:00:39
	System	15 Sep 2020 01:00:39

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-14T21:00:33', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '182bd9d3-acb6-4cbf-bec1-87b6110725b1' User entered '14 Sep 2020 21:00'	System	15 Sep 2020 01:00:39
	System	15 Sep 2020 01:00:39

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	09 Sep 2020 20:39:19
User entered 'Day 7'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:04:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-15T20:50:12', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'fd1b4263-f5ec-4c79-9b43-bcfe8c786fe6' User entered 'Yes (Y)'	System	16 Sep 2020 00:50:30
	System	16 Sep 2020 00:50:30

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:04:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-15T20:50:19', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'fd1b4263-f5ec-4c79-9b43-bcfe8c786fe6' User entered '97.3'	System	16 Sep 2020 00:50:30
	System	16 Sep 2020 00:50:30

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:04:59

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-15T20:50:23', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'fd1b4263-f5ec-4c79-9b43-bcfe8c786fe6'	System	16 Sep 2020 00:50:30
User entered 'No (N)'	System	16 Sep 2020 00:50:30

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-15T20:50:27', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'fd1b4263-f5ec-4c79-9b43-bcfe8c786fe6' User entered '15 Sep 2020 20:50'	System	16 Sep 2020 00:50:30
	System	16 Sep 2020 00:50:30

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	09 Sep 2020 20:39:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-09T17:02:23', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '62ba5d9b-e91d-42c2-87dd-e3c528e41fda' User entered 'None (1)'	System	09 Sep 2020 21:02:46
	System	09 Sep 2020 21:02:46

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-09T17:02:27', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '62ba5d9b-e91d-42c2-87dd-e3c528e41fda' User entered 'No (N)'	System	09 Sep 2020 21:02:46
	System	09 Sep 2020 21:02:46

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-09T17:02:34', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '62ba5d9b-e91d-42c2-87dd-e3c528e41fda' User entered 'No (N)'	System	09 Sep 2020 21:02:46
	System	09 Sep 2020 21:02:46

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-09T17:02:39', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '62ba5d9b-e91d-42c2-87dd-e3c528e41fda' User entered 'None (1)'	System	09 Sep 2020 21:02:46
	System	09 Sep 2020 21:02:46

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-09T17:02:43', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '62ba5d9b-e91d-42c2-87dd-e3c528e41fda' User entered '09 Sep 2020 17:02'	System	09 Sep 2020 21:02:46
	System	09 Sep 2020 21:02:46

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '09 Sep 2020 16:50'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '09 Sep 2020 19:20'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	09 Sep 2020 20:39:19
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '09 Sep 2020 20:15'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	09 Sep 2020 20:39:19
User entered 'Day 2'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:04:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-10T21:04:07', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '909d8d18-7dd8-438f-be14-c222b1452906'	System	11 Sep 2020 01:04:29
User entered 'None (1)'	System	11 Sep 2020 01:04:29

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:04:59

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-10T21:04:11', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '909d8d18-7dd8-438f-be14-c222b1452906'	System	11 Sep 2020 01:04:29
User entered 'No (N)'	System	11 Sep 2020 01:04:29

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:04:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-10T21:04:15', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '909d8d18-7dd8-438f-be14-c222b1452906'	System	11 Sep 2020 01:04:29
User entered 'No (N)'	System	11 Sep 2020 01:04:29

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:04:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-10T21:04:19', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '909d8d18-7dd8-438f-be14-c222b1452906'	System	11 Sep 2020 01:04:29
User entered 'None (1)'	System	11 Sep 2020 01:04:29

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-10T21:04:27', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '909d8d18-7dd8-438f-be14-c222b1452906'	System	11 Sep 2020 01:04:29
User entered '10 Sep 2020 21:04'	System	11 Sep 2020 01:04:29

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	09 Sep 2020 20:39:19
User entered 'Day 3'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:04:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-11T18:56:27', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '6ed5b864-5e75-4976-809f-6281bf4d4ba4'	System	11 Sep 2020 22:56:42
User entered 'None (1)'	System	11 Sep 2020 22:56:42

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:04:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-11T18:56:30', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '6ed5b864-5e75-4976-809f-6281bf4d4ba4'	System	11 Sep 2020 22:56:42
User entered 'No (N)'	System	11 Sep 2020 22:56:42

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:04:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-11T18:56:33', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '6ed5b864-5e75-4976-809f-6281bf4d4ba4'	System	11 Sep 2020 22:56:42
User entered 'No (N)'	System	11 Sep 2020 22:56:42

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:04:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-11T18:56:36', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '6ed5b864-5e75-4976-809f-6281bf4d4ba4'	System	11 Sep 2020 22:56:42
User entered 'None (1)'	System	11 Sep 2020 22:56:42

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-11T18:56:39', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '6ed5b864-5e75-4976-809f-6281bf4d4ba4'	System	11 Sep 2020 22:56:42
User entered '11 Sep 2020 18:56'	System	11 Sep 2020 22:56:42

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	09 Sep 2020 20:39:19
User entered 'Day 4'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:04:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-12T21:49:23', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '16fe164d-1185-42c5-af5f-4c527b2cb658'	System	13 Sep 2020 01:50:13
User entered 'None (1)'	System	13 Sep 2020 01:50:13

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:04:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-12T21:49:27', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '16fe164d-1185-42c5-af5f-4c527b2cb658'	System	13 Sep 2020 01:50:13
User entered 'No (N)'	System	13 Sep 2020 01:50:13

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:04:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-12T21:49:51', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '16fe164d-1185-42c5-af5f-4c527b2cb658'	System	13 Sep 2020 01:50:13
User entered 'No (N)'	System	13 Sep 2020 01:50:13

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:04:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-12T21:50:00', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '16fe164d-1185-42c5-af5f-4c527b2cb658'	System	13 Sep 2020 01:50:13
User entered 'None (1)'	System	13 Sep 2020 01:50:13

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-12T21:50:10', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '16fe164d-1185-42c5-af5f-4c527b2cb658'	System	13 Sep 2020 01:50:13
User entered '12 Sep 2020 21:50'	System	13 Sep 2020 01:50:13

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	09 Sep 2020 20:39:19
User entered 'Day 5'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:04:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-13T20:31:40', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '89013801-d680-4c75-ab51-74bb1911c4cc'	System	14 Sep 2020 00:31:59
User entered 'None (1)'	System	14 Sep 2020 00:31:59

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:04:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-13T20:31:43', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '89013801-d680-4c75-ab51-74bb1911c4cc'	System	14 Sep 2020 00:31:59
User entered 'No (N)'	System	14 Sep 2020 00:31:59

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:04:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-13T20:31:46', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '89013801-d680-4c75-ab51-74bb1911c4cc' User entered 'No (N)'	System	14 Sep 2020 00:31:59
	System	14 Sep 2020 00:31:59

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:04:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-13T20:31:49', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '89013801-d680-4c75-ab51-74bb1911c4cc'	System	14 Sep 2020 00:31:59
User entered 'None (1)'	System	14 Sep 2020 00:31:59

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-13T20:31:55', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '89013801-d680-4c75-ab51-74bb1911c4cc' User entered '13 Sep 2020 20:31'	System	14 Sep 2020 00:31:59
	System	14 Sep 2020 00:31:59

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	09 Sep 2020 20:39:19
User entered 'Day 6'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:04:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-14T21:00:37', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '22e2a718-760a-4fad-b894-b086f9a2cbd4'	System	15 Sep 2020 01:00:53
User entered 'None (1)'	System	15 Sep 2020 01:00:53

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:04:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-14T21:00:40', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '22e2a718-760a-4fad-b894-b086f9a2cbd4' User entered 'No (N)'	System	15 Sep 2020 01:00:53
	System	15 Sep 2020 01:00:53

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:04:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-14T21:00:44', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '22e2a718-760a-4fad-b894-b086f9a2cbd4' User entered 'No (N)'	System	15 Sep 2020 01:00:53
	System	15 Sep 2020 01:00:53

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:04:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-14T21:00:47', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '22e2a718-760a-4fad-b894-b086f9a2cbd4' User entered 'None (1)'	System	15 Sep 2020 01:00:53
	System	15 Sep 2020 01:00:53

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-14T21:00:51', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '22e2a718-760a-4fad-b894-b086f9a2cbd4' User entered '14 Sep 2020 21:00'	System	15 Sep 2020 01:00:53
	System	15 Sep 2020 01:00:53

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	09 Sep 2020 20:39:19
User entered 'Day 7'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:04:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-15T20:50:33', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'd9fbb45d-2b5b-471b-99f8-876cdc0a2722'	System	16 Sep 2020 00:50:52
User entered 'None (1)'	System	16 Sep 2020 00:50:52

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:04:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-15T20:50:39', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'd9fbb45d-2b5b-471b-99f8-876cdc0a2722'	System	16 Sep 2020 00:50:52
User entered 'No (N)'	System	16 Sep 2020 00:50:52

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:04:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-15T20:50:43', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'd9fbb45d-2b5b-471b-99f8-876cdc0a2722'	System	16 Sep 2020 00:50:52
User entered 'No (N)'	System	16 Sep 2020 00:50:52

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:04:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-15T20:50:47', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'd9fbb45d-2b5b-471b-99f8-876cdc0a2722'	System	16 Sep 2020 00:50:52
User entered 'None (1)'	System	16 Sep 2020 00:50:52

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:04:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-15T20:50:50', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'd9fbb45d-2b5b-471b-99f8-876cdc0a2722'	System	16 Sep 2020 00:50:52
User entered '15 Sep 2020 20:50'	System	16 Sep 2020 00:50:52

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	09 Sep 2020 20:39:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-09T17:02:49', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '6f1d8942-12bc-4a4a-8416-56a495564889' User entered 'None (0)'	System	09 Sep 2020 21:03:16
	System	09 Sep 2020 21:03:16

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-09T17:02:51', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '6f1d8942-12bc-4a4a-8416-56a495564889' User entered 'None (0)'	System	09 Sep 2020 21:03:16
	System	09 Sep 2020 21:03:16

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-09T17:02:54', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '6f1d8942-12bc-4a4a-8416-56a495564889' User entered 'None (0)'	System	09 Sep 2020 21:03:16
	System	09 Sep 2020 21:03:16

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-09T17:02:57', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '6f1d8942-12bc-4a4a-8416-56a495564889' User entered 'None (0)'	System	09 Sep 2020 21:03:16
	System	09 Sep 2020 21:03:16

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-09T17:03:00', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '6f1d8942-12bc-4a4a-8416-56a495564889' User entered 'None (0)'	System	09 Sep 2020 21:03:16
	System	09 Sep 2020 21:03:16

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-09T17:03:03', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '6f1d8942-12bc-4a4a-8416-56a495564889' User entered 'None (0)'	System	09 Sep 2020 21:03:16
	System	09 Sep 2020 21:03:16

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-09T17:03:09', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '6f1d8942-12bc-4a4a-8416-56a495564889' User entered 'No (N)'	System	09 Sep 2020 21:03:16
	System	09 Sep 2020 21:03:16

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-09T17:03:13', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '6f1d8942-12bc-4a4a-8416-56a495564889' User entered '09 Sep 2020 17:03'	System	09 Sep 2020 21:03:16
	System	09 Sep 2020 21:03:16

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '09 Sep 2020 16:50'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '09 Sep 2020 19:20'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	09 Sep 2020 20:39:19
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '09 Sep 2020 20:15'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	09 Sep 2020 20:39:19
User entered 'Day 2'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-10T21:04:34', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '791600ad-4880-4836-ad78-646edb561f69' User entered 'None (0)'	System	11 Sep 2020 01:05:15
	System	11 Sep 2020 01:05:15

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-10T21:04:39', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '791600ad-4880-4836-ad78-646edb561f69' User entered 'None (0)'	System	11 Sep 2020 01:05:15
	System	11 Sep 2020 01:05:15

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-10T21:04:45', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '791600ad-4880-4836-ad78-646edb561f69'	System	11 Sep 2020 01:05:15
User entered 'No interference with activity (1)'	System	11 Sep 2020 01:05:15

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-10T21:04:49', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '791600ad-4880-4836-ad78-646edb561f69' User entered 'None (0)'	System	11 Sep 2020 01:05:15
	System	11 Sep 2020 01:05:15

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-10T21:04:52', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '791600ad-4880-4836-ad78-646edb561f69' User entered 'None (0)'	System	11 Sep 2020 01:05:15
	System	11 Sep 2020 01:05:15

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-10T21:04:57', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '791600ad-4880-4836-ad78-646edb561f69' User entered 'None (0)'	System	11 Sep 2020 01:05:15
	System	11 Sep 2020 01:05:15

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-10T21:05:09', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '791600ad-4880-4836-ad78-646edb561f69' User entered 'No (N)'	System	11 Sep 2020 01:05:15
	System	11 Sep 2020 01:05:15

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-10T21:05:12', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '791600ad-4880-4836-ad78-646edb561f69' User entered '10 Sep 2020 21:05'	System	11 Sep 2020 01:05:15
	System	11 Sep 2020 01:05:15

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	09 Sep 2020 20:39:19
User entered 'Day 3'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-11T18:56:43', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'dea59b20-a309-4613-83ab-5d67b5e11774' User entered 'None (0)'	System	11 Sep 2020 22:57:13
	System	11 Sep 2020 22:57:13

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-11T18:56:46', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'dea59b20-a309-4613-83ab-5d67b5e11774' User entered 'None (0)'	System	11 Sep 2020 22:57:13
	System	11 Sep 2020 22:57:13

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-11T18:56:50', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'dea59b20-a309-4613-83ab-5d67b5e11774' User entered 'None (0)'	System	11 Sep 2020 22:57:13
	System	11 Sep 2020 22:57:13

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-11T18:56:53', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'dea59b20-a309-4613-83ab-5d67b5e11774' User entered 'None (0)'	System	11 Sep 2020 22:57:13
	System	11 Sep 2020 22:57:13

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-11T18:56:55', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'dea59b20-a309-4613-83ab-5d67b5e11774' User entered 'None (0)'	System	11 Sep 2020 22:57:13
	System	11 Sep 2020 22:57:13

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-11T18:56:57', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'dea59b20-a309-4613-83ab-5d67b5e11774' User entered 'None (0)'	System	11 Sep 2020 22:57:13
	System	11 Sep 2020 22:57:13

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-11T18:57:02', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'dea59b20-a309-4613-83ab-5d67b5e11774'	System	11 Sep 2020 22:57:13
User entered 'No (N)'	System	11 Sep 2020 22:57:13

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-11T18:57:05', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'dea59b20-a309-4613-83ab-5d67b5e11774'	System	11 Sep 2020 22:57:13
User entered '11 Sep 2020 18:57'	System	11 Sep 2020 22:57:13

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	09 Sep 2020 20:39:19
User entered 'Day 4'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-12T21:50:16', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '6222a1bd-3f04-4795-a80f-0b25a0113b06' User entered 'None (0)'	System	13 Sep 2020 01:51:17
	System	13 Sep 2020 01:51:17

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-12T21:50:18', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '6222a1bd-3f04-4795-a80f-0b25a0113b06' User entered 'None (0)'	System	13 Sep 2020 01:51:17
	System	13 Sep 2020 01:51:17

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-12T21:50:21', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '6222a1bd-3f04-4795-a80f-0b25a0113b06' User entered 'None (0)'	System	13 Sep 2020 01:51:17
	System	13 Sep 2020 01:51:17

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-12T21:50:23', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '6222a1bd-3f04-4795-a80f-0b25a0113b06' User entered 'None (0)'	System	13 Sep 2020 01:51:17
	System	13 Sep 2020 01:51:17

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-12T21:50:26', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '6222a1bd-3f04-4795-a80f-0b25a0113b06' User entered 'None (0)'	System	13 Sep 2020 01:51:17
	System	13 Sep 2020 01:51:17

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-12T21:50:30', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '6222a1bd-3f04-4795-a80f-0b25a0113b06' User entered 'None (0)'	System	13 Sep 2020 01:51:17
	System	13 Sep 2020 01:51:17

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-12T21:50:36', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '6222a1bd-3f04-4795-a80f-0b25a0113b06' User entered 'No (N)'	System	13 Sep 2020 01:51:17
	System	13 Sep 2020 01:51:17

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-12T21:50:44', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '6222a1bd-3f04-4795-a80f-0b25a0113b06' User entered '12 Sep 2020 21:50'	System	13 Sep 2020 01:51:17
	System	13 Sep 2020 01:51:17

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	09 Sep 2020 20:39:19
User entered 'Day 5'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-13T20:32:00', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '5556d998-4853-4a4d-869a-236f00b7006e' User entered 'None (0)'	System	14 Sep 2020 00:32:25
	System	14 Sep 2020 00:32:25

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-13T20:32:02', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '5556d998-4853-4a4d-869a-236f00b7006e' User entered 'None (0)'	System	14 Sep 2020 00:32:25
	System	14 Sep 2020 00:32:25

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-13T20:32:05', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '5556d998-4853-4a4d-869a-236f00b7006e' User entered 'None (0)'	System	14 Sep 2020 00:32:25
	System	14 Sep 2020 00:32:25

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-13T20:32:07', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '5556d998-4853-4a4d-869a-236f00b7006e' User entered 'None (0)'	System	14 Sep 2020 00:32:25
	System	14 Sep 2020 00:32:25

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-13T20:32:10', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '5556d998-4853-4a4d-869a-236f00b7006e' User entered 'None (0)'	System	14 Sep 2020 00:32:25
	System	14 Sep 2020 00:32:25

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-13T20:32:12', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '5556d998-4853-4a4d-869a-236f00b7006e' User entered 'None (0)'	System	14 Sep 2020 00:32:25
	System	14 Sep 2020 00:32:25

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-13T20:32:17', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '5556d998-4853-4a4d-869a-236f00b7006e' User entered 'No (N)'	System	14 Sep 2020 00:32:25
	System	14 Sep 2020 00:32:25

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-13T20:32:21', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '5556d998-4853-4a4d-869a-236f00b7006e' User entered '13 Sep 2020 20:32'	System	14 Sep 2020 00:32:25
	System	14 Sep 2020 00:32:25

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	09 Sep 2020 20:39:19
User entered 'Day 6'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-14T21:00:54', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'bebff508-7d64-4330-8277-4501d35b6c7e' User entered 'None (0)'	System	15 Sep 2020 01:01:15
	System	15 Sep 2020 01:01:15

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-14T21:00:56', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'bebff508-7d64-4330-8277-4501d35b6c7e' User entered 'None (0)'	System	15 Sep 2020 01:01:15
	System	15 Sep 2020 01:01:15

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-14T21:00:59', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'bebff508-7d64-4330-8277-4501d35b6c7e' User entered 'None (0)'	System	15 Sep 2020 01:01:15
	System	15 Sep 2020 01:01:15

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-14T21:01:02', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'bebff508-7d64-4330-8277-4501d35b6c7e' User entered 'None (0)'	System	15 Sep 2020 01:01:15
	System	15 Sep 2020 01:01:15

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-14T21:01:04', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'bebff508-7d64-4330-8277-4501d35b6c7e' User entered 'None (0)'	System	15 Sep 2020 01:01:15
	System	15 Sep 2020 01:01:15

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-14T21:01:06', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'bebff508-7d64-4330-8277-4501d35b6c7e' User entered 'None (0)'	System	15 Sep 2020 01:01:15
	System	15 Sep 2020 01:01:15

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-14T21:01:10', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'bebff508-7d64-4330-8277-4501d35b6c7e' User entered 'No (N)'	System	15 Sep 2020 01:01:15
	System	15 Sep 2020 01:01:15

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-14T21:01:13', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'bebff508-7d64-4330-8277-4501d35b6c7e' User entered '14 Sep 2020 21:01'	System	15 Sep 2020 01:01:15
	System	15 Sep 2020 01:01:15

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	09 Sep 2020 20:39:19
User entered 'Day 7'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-15T20:50:55', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '0c87eff9-a395-4e2c-81f2-3695ee9fb0c1' User entered 'None (0)'	System	16 Sep 2020 00:51:22
	System	16 Sep 2020 00:51:22

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-15T20:50:59', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '0c87eff9-a395-4e2c-81f2-3695ee9fb0c1' User entered 'None (0)'	System	16 Sep 2020 00:51:22
	System	16 Sep 2020 00:51:22

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-15T20:51:01', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '0c87eff9-a395-4e2c-81f2-3695ee9fb0c1' User entered 'None (0)'	System	16 Sep 2020 00:51:22
	System	16 Sep 2020 00:51:22

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-15T20:51:04', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '0c87eff9-a395-4e2c-81f2-3695ee9fb0c1' User entered 'None (0)'	System	16 Sep 2020 00:51:22
	System	16 Sep 2020 00:51:22

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-15T20:51:06', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '0c87eff9-a395-4e2c-81f2-3695ee9fb0c1' User entered 'None (0)'	System	16 Sep 2020 00:51:22
	System	16 Sep 2020 00:51:22

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-15T20:51:10', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '0c87eff9-a395-4e2c-81f2-3695ee9fb0c1' User entered 'None (0)'	System	16 Sep 2020 00:51:22
	System	16 Sep 2020 00:51:22

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-15T20:51:17', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '0c87eff9-a395-4e2c-81f2-3695ee9fb0c1' User entered 'No (N)'	System	16 Sep 2020 00:51:22
	System	16 Sep 2020 00:51:22

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-09-15T20:51:20', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '0c87eff9-a395-4e2c-81f2-3695ee9fb0c1' User entered '15 Sep 2020 20:51'	System	16 Sep 2020 00:51:22
	System	16 Sep 2020 00:51:22

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 20:39:19

US3832150

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 20:39:19

US3832150

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	16 Sep 2020 21:33:05

US3832150

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '16 Sep 2020'	Alyssa-Kay Peay (b) (4)	16 Sep 2020 21:33:05

US3832150

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4)	16 Sep 2020 21:33:05

US3832150

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered empty.	Alyssa-Kay Peay (b) (4)	16 Sep 2020 21:33:05

US3832150

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	16 Sep 2020 21:33:10

US3832150

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:37
User entered 'I'	System	16 Sep 2020 21:33:10

US3832150

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered 'Yes (Y)'	Emma Partin (b) (4)	23 Sep 2020 20:51:21

US3832150

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered '23 Sep 2020'	Emma Partin (b) (4)	23 Sep 2020 20:51:21

US3832150

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered 'Contact Made (CONTACT MADE)'	Emma Partin (b) (4)	23 Sep 2020 20:51:21

US3832150

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered empty.	Emma Partin (b) (4)	23 Sep 2020 20:51:21

US3832150

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered 'Yes (Y)'	Emma Partin (b) (4)	23 Sep 2020 20:51:24

US3832150

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:37
User entered 'I'	System	23 Sep 2020 20:51:24

US3832150

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	30 Sep 2020 18:12:05

US3832150

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered '30 Sep 2020'	Alyssa-Kay Peay (b) (4)	30 Sep 2020 18:12:05

US3832150

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4)	30 Sep 2020 18:12:05

US3832150

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered empty.	Alyssa-Kay Peay (b) (4)	30 Sep 2020 18:12:05

US3832150

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:42
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	30 Sep 2020 18:12:10

US3832150

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:37
User entered 'I'	System	30 Sep 2020 18:12:10

US3832150

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Yes (Y)'	Emma Partin (b) (4)	07 Oct 2020 20:16:34

US3832150

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:59

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '7 Oct 2020'	Emma Partin (b) (4)	07 Oct 2020 20:16:34

US3832150

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:59

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Clinic (Clinic)'	Emma Partin (b) (4)	07 Oct 2020 20:16:34

US3832150

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered 'VISIT3'	System	07 Oct 2020 20:16:34

US3832150

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Yes (Y)'	Emma Partin (b) (4)	07 Oct 2020 20:17:18

US3832150

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '7 Oct 2020'	Emma Partin (b) (4)	07 Oct 2020 20:17:18

US3832150

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '15:51'	Emma Partin (b) (4)	07 Oct 2020 20:17:18

US3832150

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered '7 Oct 2020 15:51'	System	07 Oct 2020 20:17:18

US3832150

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '97.7' F	Emma Partin (b) (4)	07 Oct 2020 20:17:18

US3832150

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Oral (Oral)'	Emma Partin (b) (4)	07 Oct 2020 20:17:18

US3832150

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered empty.	Emma Partin (b) (4)	07 Oct 2020 20:17:18

US3832150

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '76'	Emma Partin (b) (4)	07 Oct 2020 20:17:18

US3832150

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered 'bpm'	System	07 Oct 2020 20:17:18

US3832150

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '12'	Emma Partin (b) (4)	07 Oct 2020 20:17:18

US3832150

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered 'breaths/min'	System	07 Oct 2020 20:17:18

US3832150

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '106'	Emma Partin (b) (4)	07 Oct 2020 20:17:18

US3832150

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered 'mmHg'	System	07 Oct 2020 20:17:18

US3832150

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '73'	Emma Partin (b) (4)	07 Oct 2020 20:17:18

US3832150

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered 'mmHg'	System	07 Oct 2020 20:17:18

US3832150

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58

US3832150

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58

US3832150

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:04:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Yes (Y)'	Emma Partin (b) (4)	07 Oct 2020 20:17:28

US3832150

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:04:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '7 Oct 2020'	Emma Partin (b) (4)	07 Oct 2020 20:17:28

US3832150

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Response noted as " Sample was collected", however the initiated Illness visit folder is still blank and not reflecting with corresponding SARS-CoV-2 serum sample dated 16 NOV 2020, please verify and update the data as needed, or provide clarification. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Dec 2020 11:29:11
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Response noted as " Sample was collected", however the initiated Illness visit folder is still blank and not reflecting with corresponding SARS-CoV-2 serum sample dated 16 NOV 2020, please verify and update the data as needed, or provide clarification. Thank you. ' answered with 'data updated' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	16 Dec 2020 00:07:31
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Response noted as " Sample was collected", however the initiated Illness visit folder is still blank and not reflecting with corresponding SARS-CoV-2 serum sample dated 16 NOV 2020, please verify and update the data as needed, or provide clarification. Thank you. ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 10:15:04
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 16 NOV 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit or provide clarification, thank you.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 10:15:04

US3832150

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 16 NOV 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit or provide clarification, thank you.' answered with 'Sample was collected' (Site from DM).	Danyel Johnson (b) (4)	14 Dec 2020 14:03:56
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 16 NOV 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit or provide clarification, thank you.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 08:36:43
User entered 'Yes (Y)'	Emma Partin (b) (4)	07 Oct 2020 20:17:41

US3832150

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '7 Oct 2020'	Emma Partin (b) (4)	07 Oct 2020 20:17:41

US3832150

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:59

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered '16:03'	Emma Partin (b) (4)	07 Oct 2020 20:17:41

US3832150

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered '7 Oct 2020 16:03'	System	07 Oct 2020 20:17:41

US3832150

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:17:52
User entered 'Yes (Y)'	Emma Partin (b) (4)	07 Oct 2020 20:17:45

US3832150

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered 'I'	System	07 Oct 2020 20:17:45

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	10 Aug 2020 20:43:57
User entered 'Day 64'	System	10 Aug 2020 20:43:57

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-10-11T20:48:33', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'e21a6773-d2dd-47dd-8bfe-11ffeab336df'	System	12 Oct 2020 00:48:48
User entered 'No (N)'	System	12 Oct 2020 00:48:48

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-10-11T20:48:41', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'e21a6773-d2dd-47dd-8bfe-11ffeab336df'	System	12 Oct 2020 00:48:48
User entered 'No (N)'	System	12 Oct 2020 00:48:48

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-10-11T20:48:47', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'e21a6773-d2dd-47dd-8bfe-11ffeab336df' User entered '11 Oct 2020 20:48:47'	System	12 Oct 2020 00:48:48
	System	12 Oct 2020 00:48:48

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	10 Aug 2020 20:43:57
User entered '10 Oct 2020 00:01'	System	10 Aug 2020 20:43:57

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	10 Aug 2020 20:43:57
User entered '14 Oct 2020 23:59'	System	10 Aug 2020 20:43:57

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	10 Aug 2020 20:43:57
User entered 'Day 71'	System	10 Aug 2020 20:43:57

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-10-18T09:25:53', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'dd7d68c2-b07f-499a-a89b-036a8717b54e'	System	18 Oct 2020 13:26:06
User entered 'No (N)'	System	18 Oct 2020 13:26:06

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-10-18T09:26:00', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'dd7d68c2-b07f-499a-a89b-036a8717b54e'	System	18 Oct 2020 13:26:06
User entered 'No (N)'	System	18 Oct 2020 13:26:06

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-10-18T09:26:04', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'dd7d68c2-b07f-499a-a89b-036a8717b54e' User entered '18 Oct 2020 09:26:04'	System	18 Oct 2020 13:26:06
	System	18 Oct 2020 13:26:06

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	10 Aug 2020 20:43:57
User entered '17 Oct 2020 00:01'	System	10 Aug 2020 20:43:57

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	10 Aug 2020 20:43:57
User entered '21 Oct 2020 23:59'	System	10 Aug 2020 20:43:57

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	10 Aug 2020 20:43:57
User entered 'Day 78'	System	10 Aug 2020 20:43:57

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-10-25T07:38:22', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '3bf3e8e5-043f-47f6-a10b-53acc11c2090'	System	25 Oct 2020 11:38:37
User entered 'No (N)'	System	25 Oct 2020 11:38:37

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-10-25T07:38:30', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '3bf3e8e5-043f-47f6-a10b-53acc11c2090'	System	25 Oct 2020 11:38:37
User entered 'No (N)'	System	25 Oct 2020 11:38:37

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-10-25T07:38:35', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '3bf3e8e5-043f-47f6-a10b-53acc11c2090' User entered '25 Oct 2020 07:38:35'	System	25 Oct 2020 11:38:37
	System	25 Oct 2020 11:38:37

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	10 Aug 2020 20:43:57
User entered '24 Oct 2020 00:01'	System	10 Aug 2020 20:43:57

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	10 Aug 2020 20:43:57
User entered '28 Oct 2020 23:59'	System	10 Aug 2020 20:43:57

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	10 Aug 2020 20:43:57
User entered 'Day 92'	System	10 Aug 2020 20:43:57

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-11-08T12:27:28', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '4e325075-12e6-40d2-8ebd-3069c48a447f' User entered 'No (N)'	System	08 Nov 2020 17:27:40
	System	08 Nov 2020 17:27:40

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-11-08T12:27:35', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '4e325075-12e6-40d2-8ebd-3069c48a447f'	System	08 Nov 2020 17:27:40
User entered 'No (N)'	System	08 Nov 2020 17:27:40

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-11-08T12:27:39', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '4e325075-12e6-40d2-8ebd-3069c48a447f' User entered '08 Nov 2020 12:27:39'	System	08 Nov 2020 17:27:40
	System	08 Nov 2020 17:27:40

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	10 Aug 2020 20:43:57
User entered '07 Nov 2020 00:01'	System	10 Aug 2020 20:43:57

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	10 Aug 2020 20:43:57
User entered '11 Nov 2020 23:59'	System	10 Aug 2020 20:43:57

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	10 Aug 2020 20:43:57
User entered 'Day 99'	System	10 Aug 2020 20:43:57

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-11-14T08:12:43', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '8767020a-6d3c-481f-8558-989acc63fe63' User entered 'Yes (Y)'	System	14 Nov 2020 13:18:17
	System	14 Nov 2020 13:18:17

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-11-14T08:13:37', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '8767020a-6d3c-481f-8558-989acc63fe63' User entered 'No (N)'	System	14 Nov 2020 13:18:17
	System	14 Nov 2020 13:18:17

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-11-14T08:14:52', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '8767020a-6d3c-481f-8558-989acc63fe63'	System	14 Nov 2020 13:18:17
User entered 'Yes (Y)'	System	14 Nov 2020 13:18:17

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-11-14T08:15:53', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '8767020a-6d3c-481f-8558-989acc63fe63' User entered '0'	System	14 Nov 2020 13:18:17
	System	14 Nov 2020 13:18:17

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-11-14T08:15:53', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '8767020a-6d3c-481f-8558-989acc63fe63' User entered '1'	System	14 Nov 2020 13:18:17
	System	14 Nov 2020 13:18:17

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-11-14T08:15:53', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '8767020a-6d3c-481f-8558-989acc63fe63' User entered '0'	System	14 Nov 2020 13:18:17
	System	14 Nov 2020 13:18:17

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-11-14T08:15:53', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '8767020a-6d3c-481f-8558-989acc63fe63' User entered '0'	System	14 Nov 2020 13:18:17
	System	14 Nov 2020 13:18:17

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-11-14T08:15:53', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '8767020a-6d3c-481f-8558-989acc63fe63' User entered '0'	System	14 Nov 2020 13:18:17
	System	14 Nov 2020 13:18:17

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-11-14T08:15:53', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '8767020a-6d3c-481f-8558-989acc63fe63' User entered '0'	System	14 Nov 2020 13:18:17
	System	14 Nov 2020 13:18:17

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-11-14T08:15:53', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '8767020a-6d3c-481f-8558-989acc63fe63' User entered '0'	System	14 Nov 2020 13:18:17
	System	14 Nov 2020 13:18:17

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-11-14T08:15:53', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '8767020a-6d3c-481f-8558-989acc63fe63' User entered '0'	System	14 Nov 2020 13:18:17
	System	14 Nov 2020 13:18:17

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-11-14T08:15:53', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '8767020a-6d3c-481f-8558-989acc63fe63' User entered '1'	System	14 Nov 2020 13:18:17
	System	14 Nov 2020 13:18:17

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-11-14T08:15:53', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '8767020a-6d3c-481f-8558-989acc63fe63' User entered '0'	System	14 Nov 2020 13:18:17
	System	14 Nov 2020 13:18:17

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-11-14T08:15:53', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '8767020a-6d3c-481f-8558-989acc63fe63' User entered '0'	System	14 Nov 2020 13:18:17
	System	14 Nov 2020 13:18:17

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-11-14T08:15:53', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '8767020a-6d3c-481f-8558-989acc63fe63' User entered '1'	System	14 Nov 2020 13:18:17
	System	14 Nov 2020 13:18:17

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-11-14T08:15:53', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '8767020a-6d3c-481f-8558-989acc63fe63' User entered '1'	System	14 Nov 2020 13:18:17
	System	14 Nov 2020 13:18:17

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-11-14T08:15:53', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '8767020a-6d3c-481f-8558-989acc63fe63' User entered '1'	System	14 Nov 2020 13:18:17
	System	14 Nov 2020 13:18:17

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-11-14T08:15:53', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '8767020a-6d3c-481f-8558-989acc63fe63' User entered '0'	System	14 Nov 2020 13:18:17
	System	14 Nov 2020 13:18:17

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-11-14T08:15:53', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '8767020a-6d3c-481f-8558-989acc63fe63' User entered '0'	System	14 Nov 2020 13:18:17
	System	14 Nov 2020 13:18:17

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-11-14T08:15:53', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '8767020a-6d3c-481f-8558-989acc63fe63' User entered '0'	System	14 Nov 2020 13:18:17
	System	14 Nov 2020 13:18:17

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-11-14T08:17:05', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '8767020a-6d3c-481f-8558-989acc63fe63'	System	14 Nov 2020 13:18:17
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Nov 2020 13:18:17

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-11-14T08:17:13', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '8767020a-6d3c-481f-8558-989acc63fe63' User entered 'No (N)'	System	14 Nov 2020 13:18:17
	System	14 Nov 2020 13:18:17

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-11-14T08:17:30', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '8767020a-6d3c-481f-8558-989acc63fe63' User entered '14 Nov 2020 08:17:30'	System	14 Nov 2020 13:18:17
	System	14 Nov 2020 13:18:17

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	10 Aug 2020 20:43:57
User entered '14 Nov 2020 00:01'	System	10 Aug 2020 20:43:57

US3832150

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:54:23
Data entry locked.	System	10 Aug 2020 20:43:57
User entered '18 Nov 2020 23:59'	System	10 Aug 2020 20:43:57

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-11-21T07:50:36', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'aa21a4bf-05bb-4dd9-a543-ed6e7c45101d'	System	21 Nov 2020 12:51:28
User entered 'Yes (Y)'	System	21 Nov 2020 12:51:28

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Have you been exposed to someone with 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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-11-21T07:50:47', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'aa21a4bf-05bb-4dd9-a543-ed6e7c45101d'	System	21 Nov 2020 12:51:28
User entered 'No (N)'	System	21 Nov 2020 12:51:28

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-11-21T07:50:53', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'aa21a4bf-05bb-4dd9-a543-ed6e7c45101d'	System	21 Nov 2020 12:51:28
User entered 'No (N)'	System	21 Nov 2020 12:51:28

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-11-21T07:51:00', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'aa21a4bf-05bb-4dd9-a543-ed6e7c45101d'	System	21 Nov 2020 12:51:28
User entered 'No (N)'	System	21 Nov 2020 12:51:28

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-11-21T07:51:26', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'aa21a4bf-05bb-4dd9-a543-ed6e7c45101d' User entered '21 Nov 2020 07:51:26'	System	21 Nov 2020 12:51:28
	System	21 Nov 2020 12:51:28

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-11-25T07:22:31', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'a0655c35-a959-40fb-a11c-0fb0594bdbbc7' User entered 'No (N)'	System	25 Nov 2020 12:22:46
	System	25 Nov 2020 12:22:46

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Have you been exposed to someone with 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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-11-25T07:22:37', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'a0655c35-a959-40fb-a11c-0fb0594bdb7'	System	25 Nov 2020 12:22:46
User entered 'No (N)'	System	25 Nov 2020 12:22:46

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-11-25T07:22:42', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'a0655c35-a959-40fb-a11c-0fb0594bdbbc7' User entered '25 Nov 2020 07:22:42'	System	25 Nov 2020 12:22:46
	System	25 Nov 2020 12:22:46

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-12-09T06:38:45', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '23f09d02-fccf-46aa-b28a-20d43e7ca2b4'	System	09 Dec 2020 11:39:01
User entered 'No (N)'	System	09 Dec 2020 11:39:01

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Have you been exposed to someone with 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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-12-09T06:38:51', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '23f09d02-fccf-46aa-b28a-20d43e7ca2b4'	System	09 Dec 2020 11:39:01
User entered 'No (N)'	System	09 Dec 2020 11:39:01

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-12-09T06:38:55', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '23f09d02-fccf-46aa-b28a-20d43e7ca2b4' User entered '09 Dec 2020 06:38:55'	System	09 Dec 2020 11:39:01
	System	09 Dec 2020 11:39:01

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-12-16T12:37:06', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '9beea7b0-3c10-4355-9029-8b4e700b6d4d'	System	16 Dec 2020 17:37:24
User entered 'No (N)'	System	16 Dec 2020 17:37:24

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Have you been exposed to someone with 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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-12-16T12:37:13', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '9beea7b0-3c10-4355-9029-8b4e700b6d4d'	System	16 Dec 2020 17:37:24
User entered 'No (N)'	System	16 Dec 2020 17:37:24

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-12-16T12:37:18', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '9beea7b0-3c10-4355-9029-8b4e700b6d4d' User entered '16 Dec 2020 12:37:18'	System	16 Dec 2020 17:37:24
	System	16 Dec 2020 17:37:24

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-12-23T13:09:58', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'c6d27771-47e1-4e09-bfb2-522da23af7de' User entered 'No (N)'	System	23 Dec 2020 18:10:12
	System	23 Dec 2020 18:10:12

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Have you been exposed to someone with 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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-12-23T13:10:04', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'c6d27771-47e1-4e09-bfb2-522da23af7de' User entered 'No (N)'	System	23 Dec 2020 18:10:12

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-12-23T13:10:07', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'c6d27771-47e1-4e09-bfb2-522da23af7de' User entered '23 Dec 2020 13:10:07'	System	23 Dec 2020 18:10:12
	System	23 Dec 2020 18:10:12

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-12-30T08:14:30', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '2e99520f-d075-44ee-ac93-cb767924f474' User entered 'No (N)'	System	30 Dec 2020 13:14:46
	System	30 Dec 2020 13:14:46

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Have you been exposed to someone with 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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-12-30T08:14:36', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '2e99520f-d075-44ee-ac93-cb767924f474' User entered 'No (N)'	System	30 Dec 2020 13:14:46

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2020-12-30T08:14:43', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '2e99520f-d075-44ee-ac93-cb767924f474' User entered '30 Dec 2020 08:14:43'	System	30 Dec 2020 13:14:46
	System	30 Dec 2020 13:14:46

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-01-06T17:26:44', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'a8c16e9f-44af-4651-9806-cdb4ba171e0c'	System	06 Jan 2021 22:26:56
User entered 'No (N)'	System	06 Jan 2021 22:26:56

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Have you been exposed to someone with 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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-01-06T17:26:48', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'a8c16e9f-44af-4651-9806-cdb4ba171e0c'	System	06 Jan 2021 22:26:56
User entered 'No (N)'	System	06 Jan 2021 22:26:56

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-01-06T17:26:51', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'a8c16e9f-44af-4651-9806-cdb4ba171e0c'	System	06 Jan 2021 22:26:56
User entered '06 Jan 2021 17:26:51'	System	06 Jan 2021 22:26:56

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-01-14T19:25:04', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'd32a3363-e469-4c51-8ba2-ed0462017684'	System	15 Jan 2021 00:25:19
User entered 'No (N)'	System	15 Jan 2021 00:25:19

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Have you been exposed to someone with 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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-01-14T19:25:07', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'd32a3363-e469-4c51-8ba2-ed0462017684'	System	15 Jan 2021 00:25:19
User entered 'No (N)'	System	15 Jan 2021 00:25:19

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-01-14T19:25:17', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'd32a3363-e469-4c51-8ba2-ed0462017684'	System	15 Jan 2021 00:25:19
User entered '14 Jan 2021 19:25:17'	System	15 Jan 2021 00:25:19

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-01-20T12:20:48', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '65823e70-c686-4945-b61f-98c086d0d9b5'	System	20 Jan 2021 17:21:04
User entered 'No (N)'	System	20 Jan 2021 17:21:04

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Have you been exposed to someone with 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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-01-20T12:20:53', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '65823e70-c686-4945-b61f-98c086d0d9b5'	System	20 Jan 2021 17:21:04
User entered 'No (N)'	System	20 Jan 2021 17:21:04

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-01-20T12:20:59', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '65823e70-c686-4945-b61f-98c086d0d9b5' User entered '20 Jan 2021 12:20:59'	System	20 Jan 2021 17:21:04

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-01-29T10:50:15', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '66dd9c86-b50f-468f-9c58-f0ad655e8193'	System	29 Jan 2021 15:50:28
User entered 'No (N)'	System	29 Jan 2021 15:50:28

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Have you been exposed to someone with 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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-01-29T10:50:19', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '66dd9c86-b50f-468f-9c58-f0ad655e8193'	System	29 Jan 2021 15:50:28
User entered 'No (N)'	System	29 Jan 2021 15:50:28

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-01-29T10:50:23', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '66dd9c86-b50f-468f-9c58-f0ad655e8193' User entered '29 Jan 2021 10:50:23'	System	29 Jan 2021 15:50:28
	System	29 Jan 2021 15:50:28

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-02-03T07:48:15', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '27f08595-78da-4e90-9dca-09d67439146e' User entered 'No (N)'	System	03 Feb 2021 12:48:24
	System	03 Feb 2021 12:48:24

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Have you been exposed to someone with 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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-02-03T07:48:18', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '27f08595-78da-4e90-9dca-09d67439146e' User entered 'No (N)'	System	03 Feb 2021 12:48:24
	System	03 Feb 2021 12:48:24

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-02-03T07:48:21', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '27f08595-78da-4e90-9dca-09d67439146e' User entered '03 Feb 2021 07:48:21'	System	03 Feb 2021 12:48:24
	System	03 Feb 2021 12:48:24

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-02-10T12:08:58', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '99be0821-3b18-4a74-afa7-566b8c474308' User entered 'No (N)'	System	10 Feb 2021 17:15:34
	System	10 Feb 2021 17:15:34

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Have you been exposed to someone with 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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-02-10T12:09:04', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '99be0821-3b18-4a74-afa7-566b8c474308'	System	10 Feb 2021 17:15:34
User entered 'No (N)'	System	10 Feb 2021 17:15:34

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-02-10T12:09:06', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '99be0821-3b18-4a74-afa7-566b8c474308'	System	10 Feb 2021 17:15:34
User entered '10 Feb 2021 12:09:06'	System	10 Feb 2021 17:15:34

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-02-17T08:22:21', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '693c0a89-4391-47f9-a703-2c001d53a7c4'	System	17 Feb 2021 13:22:33
User entered 'No (N)'	System	17 Feb 2021 13:22:33

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Have you been exposed to someone with 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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-02-17T08:22:27', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '693c0a89-4391-47f9-a703-2c001d53a7c4'	System	17 Feb 2021 13:22:33
User entered 'No (N)'	System	17 Feb 2021 13:22:33

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-02-17T08:22:30', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '693c0a89-4391-47f9-a703-2c001d53a7c4'	System	17 Feb 2021 13:22:33
User entered '17 Feb 2021 08:22:30'	System	17 Feb 2021 13:22:33

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-02-25T21:31:06-05:00', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '67bbf5e8-c2c1-4050-a1d3-62e1611fdb0c' User entered 'No (N)'	System	26 Feb 2021 02:39:55
	System	26 Feb 2021 02:39:55

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Have you been exposed to someone with 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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-02-25T21:31:13-05:00', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '67bbf5e8-c2c1-4050-a1d3-62e1611fdb0c'	System	26 Feb 2021 02:39:55
User entered 'No (N)'	System	26 Feb 2021 02:39:55

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-02-25T21:31:18-05:00', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '67bbf5e8-c2c1-4050-a1d3-62e1611fdb0c'	System	26 Feb 2021 02:39:55
User entered '26 Feb 2021 02:31:18'	System	26 Feb 2021 02:39:55

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-03-07T11:59:28-05:00', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '8444581d-abab-4f68-89d1-d5ca7078558a'	System	07 Mar 2021 16:59:40
User entered 'No (N)'	System	07 Mar 2021 16:59:40

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Have you been exposed to someone with 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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-03-07T11:59:31-05:00', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '8444581d-abab-4f68-89d1-d5ca7078558a'	System	07 Mar 2021 16:59:40
User entered 'No (N)'	System	07 Mar 2021 16:59:40

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-03-07T11:59:34-05:00', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '8444581d-abab-4f68-89d1-d5ca7078558a' User entered '07 Mar 2021 11:59:34'	System	07 Mar 2021 16:59:40
	System	07 Mar 2021 16:59:40

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-03-10T10:11:49-05:00', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'e284327b-008d-4b9f-b4e5-49a2dcc67c1b' User entered 'No (N)'	System	10 Mar 2021 15:11:59
	System	10 Mar 2021 15:11:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Have you been exposed to someone with 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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-03-10T10:11:52-05:00', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'e284327b-008d-4b9f-b4e5-49a2dcc67c1b'	System	10 Mar 2021 15:11:59
User entered 'No (N)'	System	10 Mar 2021 15:11:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-03-10T10:11:56-05:00', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: 'e284327b-008d-4b9f-b4e5-49a2dcc67c1b'	System	10 Mar 2021 15:11:59
User entered '10 Mar 2021 10:11:56'	System	10 Mar 2021 15:11:59

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-03-17T09:21:14-04:00', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '6ce053fa-ffb0-4991-93e9-f6065dd000e7'	System	17 Mar 2021 13:21:25
User entered 'No (N)'	System	17 Mar 2021 13:21:25

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Have you been exposed to someone with 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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-03-17T09:21:18-04:00', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '6ce053fa-ffb0-4991-93e9-f6065dd000e7'	System	17 Mar 2021 13:21:25
User entered 'No (N)'	System	17 Mar 2021 13:21:25

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-03-17T09:21:22-04:00', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '6ce053fa-ffb0-4991-93e9-f6065dd000e7'	System	17 Mar 2021 13:21:25
User entered '17 Mar 2021 09:21:22'	System	17 Mar 2021 13:21:25

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-03-24T06:44:06-04:00', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '0bd84bd8-8f67-48af-a3e4-b61fc09771b8'	System	24 Mar 2021 10:44:15
User entered 'No (N)'	System	24 Mar 2021 10:44:15

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Have you been exposed to someone with 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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-03-24T06:44:09-04:00', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '0bd84bd8-8f67-48af-a3e4-b61fc09771b8'	System	24 Mar 2021 10:44:15
User entered 'No (N)'	System	24 Mar 2021 10:44:15

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-03-24T06:44:12-04:00', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '0bd84bd8-8f67-48af-a3e4-b61fc09771b8'	System	24 Mar 2021 10:44:15
User entered '24 Mar 2021 06:44:12'	System	24 Mar 2021 10:44:15

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-03-31T06:42:46-04:00', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '2a1d4517-dade-40d6-9e39-c3cb62132e0c'	System	31 Mar 2021 10:42:58
User entered 'No (N)'	System	31 Mar 2021 10:42:58

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Have you been exposed to someone with 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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-03-31T06:42:48-04:00', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '2a1d4517-dade-40d6-9e39-c3cb62132e0c' User entered 'No (N)'	System	31 Mar 2021 10:42:58
	System	31 Mar 2021 10:42:58

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-03-31T06:42:51-04:00', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '2a1d4517-dade-40d6-9e39-c3cb62132e0c' User entered '31 Mar 2021 06:42:51'	System	31 Mar 2021 10:42:58
	System	31 Mar 2021 10:42:58

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-04-07T08:19:08-04:00', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '20b5cb00-f4b0-43c9-814b-f9114beafeb2'	System	07 Apr 2021 12:19:21
User entered 'No (N)'	System	07 Apr 2021 12:19:21

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Have you been exposed to someone with 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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-04-07T08:19:12-04:00', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '20b5cb00-f4b0-43c9-814b-f9114beafeb2'	System	07 Apr 2021 12:19:21
User entered 'No (N)'	System	07 Apr 2021 12:19:21

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-04-07T08:19:15-04:00', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '20b5cb00-f4b0-43c9-814b-f9114beafeb2'	System	07 Apr 2021 12:19:21
User entered '07 Apr 2021 08:19:15'	System	07 Apr 2021 12:19:21

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-04-14T20:56:29-04:00', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '7c447551-3e2d-49dd-bec6-2e793d19c98b'	System	15 Apr 2021 00:56:48
User entered 'No (N)'	System	15 Apr 2021 00:56:48

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Have you been exposed to someone with 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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-04-14T20:56:25-04:00', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '7c447551-3e2d-49dd-bec6-2e793d19c98b'	System	15 Apr 2021 00:56:48
User entered 'No (N)'	System	15 Apr 2021 00:56:48

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-04-14T20:56:44-04:00', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '7c447551-3e2d-49dd-bec6-2e793d19c98b'	System	15 Apr 2021 00:56:48
User entered '14 Apr 2021 20:56:44'	System	15 Apr 2021 00:56:48

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-04-22T08:43:50-04:00', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '83f2746f-fb5d-4c97-914e-43119d098ea4'	System	22 Apr 2021 12:44:02
User entered 'No (N)'	System	22 Apr 2021 12:44:02

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Have you been exposed to someone with 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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-04-22T08:43:53-04:00', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '83f2746f-fb5d-4c97-914e-43119d098ea4'	System	22 Apr 2021 12:44:02
User entered 'No (N)'	System	22 Apr 2021 12:44:02

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-04-22T08:43:56-04:00', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '83f2746f-fb5d-4c97-914e-43119d098ea4'	System	22 Apr 2021 12:44:02
User entered '22 Apr 2021 08:43:56'	System	22 Apr 2021 12:44:02

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-05-01T15:16:28-04:00', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '8a0e6590-a1e0-418f-859f-00806fddc298'	System	01 May 2021 19:16:39
User entered 'No (N)'	System	01 May 2021 19:16:39

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

Have you been exposed to someone with 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 (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-05-01T15:16:31-04:00', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '8a0e6590-a1e0-418f-859f-00806fddc298'	System	01 May 2021 19:16:39
User entered 'No (N)'	System	01 May 2021 19:16:39

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-05-01T15:16:34-04:00', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '8a0e6590-a1e0-418f-859f-00806fddc298'	System	01 May 2021 19:16:39
User entered '01 May 2021 15:16:34'	System	01 May 2021 19:16:39

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 03:06:43

US3832150

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:06:43
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 03:06:43

US3832150

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:04:59

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)	25 Apr 2021 19:35:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-03-02T16:11:47-05:00', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '75c3a4fd-7ac4-4dd6-be3d-81053c7fd485'	System	02 Mar 2021 21:12:03
User entered 'No (N)'	System	02 Mar 2021 21:12:03

US3832150

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:04:59

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:35:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C7361E5-00AE-4983-AB6E-402904650B58)', Time: '2021-03-02T16:11:59-05:00', User OID: 'PatientReportedOutcome (US3832150)', ODM File OID: '75c3a4fd-7ac4-4dd6-be3d-81053c7fd485'	System	02 Mar 2021 21:12:03
User entered '02 Mar 2021 16:11:59'	System	02 Mar 2021 21:12:03

US3832150

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4) (b) (4)	04 Nov 2020 19:41:00

US3832150

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '4 Nov 2020'	Alyssa-Kay Peay (b) (4)	04 Nov 2020 19:41:00

US3832150

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alyssa-Kay Peay (b) (4)	04 Nov 2020 19:41:00

US3832150

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered empty.	Alyssa-Kay Peay (b) (4)	04 Nov 2020 19:41:00

US3832150

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	04 Nov 2020 19:41:05

US3832150

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:08:58
User entered 'I'	System	04 Nov 2020 19:41:05

US3832150

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:02:10
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	09 Dec 2020 16:22:04

US3832150

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:02:10
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '9 Dec 2020'	Alyssa-Kay Peay (b) (4)	09 Dec 2020 16:22:04

US3832150

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:02:10
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4)	09 Dec 2020 16:22:04

US3832150

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:02:10
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered empty.	Alyssa-Kay Peay (b) (4)	09 Dec 2020 16:22:04

US3832150

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:02:10
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	09 Dec 2020 16:22:08

US3832150

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:02:10
User entered 'I'	System	09 Dec 2020 16:22:08

US3832150

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:02:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	06 Jan 2021 19:24:04

US3832150

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:02:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '6 Jan 2021'	Rodolfo Barrera (b) (4)	06 Jan 2021 19:24:04

US3832150

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:02:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Contact Made (CONTACT MADE)'	Rodolfo Barrera (b) (4)	06 Jan 2021 19:24:04

US3832150

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:02:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered empty.	Rodolfo Barrera (b) (4)	06 Jan 2021 19:24:04

US3832150

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:02:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	06 Jan 2021 19:24:10

US3832150

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:02:12
User entered 'I'	System	06 Jan 2021 19:24:10

US3832150

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:02:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	04 Feb 2021 16:12:42

US3832150

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:02:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '4 Feb 2021'	Rodolfo Barrera (b) (4)	04 Feb 2021 16:12:42

US3832150

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:02:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Contact Made (CONTACT MADE)'	Rodolfo Barrera (b) (4)	04 Feb 2021 16:12:42

US3832150

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:02:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered empty.	Rodolfo Barrera (b) (4)	04 Feb 2021 16:12:42

US3832150

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:02:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	04 Feb 2021 16:12:56

US3832150

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:02:12
User entered 'I'	System	04 Feb 2021 16:12:56

US3832150

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:56:29
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	16 Mar 2021 18:20:37

US3832150

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:59

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:56:29
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
User entered '11 Mar 2021'	Rodolfo Barrera (b) (4)	16 Mar 2021 18:20:37

US3832150

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:59

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:56:29
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
User entered 'Clinic (Clinic)'	Rodolfo Barrera (b) (4)	16 Mar 2021 18:20:37

US3832150

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:56:29
User entered 'VISIT4'	System	16 Mar 2021 18:20:37

US3832150

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:56:29
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
User entered 'No (N)'	Emma Partin (b) (4)	31 Mar 2021 12:31:46

US3832150

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:56:29
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
User entered empty.	Emma Partin (b) (4)	31 Mar 2021 12:31:46

US3832150

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:56:29
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
User entered empty.	Emma Partin (b) (4)	31 Mar 2021 12:31:46

US3832150

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:56:29
User entered empty.	System	31 Mar 2021 12:31:46

US3832150

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:56:29
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
User entered empty.	Emma Partin (b) (4)	31 Mar 2021 12:31:46

US3832150

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:56:29
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
User entered empty.	Emma Partin (b) (4)	31 Mar 2021 12:31:46

US3832150

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:56:29
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
User entered empty.	Emma Partin (b) (4)	31 Mar 2021 12:31:46

US3832150

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:56:29
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
User entered empty.	Emma Partin (b) (4)	31 Mar 2021 12:31:46

US3832150

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:56:29
User entered empty.	System	31 Mar 2021 12:31:46

US3832150

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:56:29
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
User entered empty.	Emma Partin (b) (4)	31 Mar 2021 12:31:46

US3832150

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:56:29
User entered empty.	System	31 Mar 2021 12:31:46

US3832150

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:56:29
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
User entered empty.	(b) (4)	
	Emma Partin (b) (4)	31 Mar 2021 12:31:46
	(b) (4)	

US3832150

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:56:29
User entered empty.	System	31 Mar 2021 12:31:46

US3832150

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:56:29
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
User entered empty.	Emma Partin (b) (4)	31 Mar 2021 12:31:46

US3832150

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:56:29
User entered empty.	System	31 Mar 2021 12:31:46

US3832150

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:56:29

US3832150

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:56:29

US3832150

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:04:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:56:29
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
User entered 'No (N)'	Rodolfo Barrera (b) (4)	16 Mar 2021 18:20:42

US3832150

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:04:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:56:29
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
User entered empty.	Rodolfo Barrera (b) (4)	16 Mar 2021 18:20:42

US3832150

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:56:29
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	16 Mar 2021 18:21:04

US3832150

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:56:29
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
User entered '11 Mar 2021'	Rodolfo Barrera (b) (4)	16 Mar 2021 18:21:04

US3832150

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:59

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:56:29
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
User entered '13:26'	Rodolfo Barrera (b) (4)	16 Mar 2021 18:21:04

US3832150

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:56:29
User entered '11 Mar 2021 13:26'	System	16 Mar 2021 18:21:04

US3832150

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:56:29
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	16 Mar 2021 18:21:12

US3832150

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:56:29
User entered 'I'	System	16 Mar 2021 18:21:12

US3832150

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
	(b) (4)	
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	05 Apr 2021 15:53:25
	(b) (4)	

US3832150

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
	(b) (4)	
User entered '5 Apr 2021'	Rodolfo Barrera (b) (4)	05 Apr 2021 15:53:25
	(b) (4)	

US3832150

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Rodolfo Barrera (b) (4)	05 Apr 2021 15:53:25

US3832150

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
	(b) (4)	
User entered empty.	Rodolfo Barrera (b) (4)	05 Apr 2021 15:53:25
	(b) (4)	

US3832150

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
	(b) (4)	
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	05 Apr 2021 15:53:30
	(b) (4)	

US3832150

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:59

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 15:53:30

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:04:59

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '16 Nov 2020'	Danyel Johnson (b) (4)	16 Nov 2020 16:24:53

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:04:59

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '09:00'	Danyel Johnson (b) (4)	16 Nov 2020 16:24:53

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:04:59

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User entered '16 Nov 2020 09:00'	System	16 Nov 2020 16:24:53

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:04:59

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Danyel Johnson (b) (4)	16 Nov 2020 16:24:53

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:04:59

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	16 Nov 2020 16:24:53

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:04:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Day 1 (Day 1)'	Danyel Johnson (b) (4)	16 Nov 2020 16:28:12

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:04:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '16 Nov 2020'	Danyel Johnson (b) (4)	16 Nov 2020 16:28:12

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:04:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '0'	Danyel Johnson (b) (4)	16 Nov 2020 16:28:12

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:04:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '95' reason for change: Data Entry Error	(b) (4)	
	Danyel Johnson (b) (4)	16 Nov 2020 16:40:40
User entered empty.	(b) (4)	
	Danyel Johnson (b) (4)	16 Nov 2020 16:28:12
	(b) (4)	

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:04:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User entered '%'	System	16 Nov 2020 16:40:40
User entered empty.	System	16 Nov 2020 16:28:12

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:04:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '97.0' F reason for change: Data Entry Error	System	16 Nov 2020 17:03:51
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Danyel Johnson (b) (4)	16 Nov 2020 17:03:51
User entered '97.0' (non-conformant).	(b) (4)	
User entered empty.	System	16 Nov 2020 16:40:40
	Danyel Johnson (b) (4)	16 Nov 2020 16:40:40
	(b) (4)	
	Danyel Johnson (b) (4)	16 Nov 2020 16:28:12
	(b) (4)	

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:04:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Mild (Mild)'	Danyel Johnson (b) (4)	16 Nov 2020 16:28:12

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:04:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Mild (Mild)'	Danyel Johnson (b) (4)	16 Nov 2020 16:28:12

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:04:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'None (None)'	Danyel Johnson (b) (4)	16 Nov 2020 16:28:12

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:04:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'None (None)'	Danyel Johnson (b) (4)	16 Nov 2020 16:28:12

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:04:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Mild (Mild)'	Danyel Johnson (b) (4)	16 Nov 2020 16:28:12

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:04:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'None (None)'	Danyel Johnson (b) (4)	16 Nov 2020 16:28:12

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:04:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'None (None)'	Danyel Johnson (b) (4)	16 Nov 2020 16:28:12

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:04:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Moderate (Moderate)'	Danyel Johnson (b) (4)	16 Nov 2020 16:28:12

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:04:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'None (None)'	Danyel Johnson (b) (4)	16 Nov 2020 16:28:12

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:04:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'None (None)'	Danyel Johnson (b) (4)	16 Nov 2020 16:28:12

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:04:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Moderate (Moderate)'	Danyel Johnson (b) (4)	16 Nov 2020 16:28:12

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:04:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Moderate (Moderate)'	Danyel Johnson (b) (4)	16 Nov 2020 16:28:12

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:04:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Mild (Mild)'	Danyel Johnson (b) (4)	16 Nov 2020 16:28:12

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:04:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'None (None)'	Danyel Johnson (b) (4)	16 Nov 2020 16:28:12

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:04:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'None (None)'	Danyel Johnson (b) (4)	16 Nov 2020 16:28:12

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:04:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Moderate (Moderate)'	Danyel Johnson (b) (4)	16 Nov 2020 16:28:12

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:04:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Day 2 (Day 2)'	Danyel Johnson (b) (4)	17 Nov 2020 20:00:55

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:04:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '17 Nov 2020'	Danyel Johnson (b) (4)	17 Nov 2020 20:00:55

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:04:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '0'	Danyel Johnson (b) (4)	17 Nov 2020 20:00:55

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:04:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '99'	Danyel Johnson (b) (4)	17 Nov 2020 20:00:55

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:04:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User entered '%'	System	17 Nov 2020 20:00:55

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:04:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '97.6' F	Danyel Johnson (b) (4)	17 Nov 2020 20:00:55

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:04:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'None (None)'	Danyel Johnson (b) (4)	17 Nov 2020 20:00:55

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:04:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'None (None)'	Danyel Johnson (b) (4)	17 Nov 2020 20:00:55

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:04:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'None (None)'	Danyel Johnson (b) (4)	17 Nov 2020 20:00:55

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:04:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'None (None)'	Danyel Johnson (b) (4)	17 Nov 2020 20:00:55

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:04:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'None (None)'	Danyel Johnson (b) (4)	17 Nov 2020 20:00:55

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:04:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'None (None)'	Danyel Johnson (b) (4)	17 Nov 2020 20:00:55

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:04:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'None (None)'	Danyel Johnson (b) (4)	17 Nov 2020 20:00:55

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:04:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'None (None)'	Danyel Johnson (b) (4)	17 Nov 2020 20:00:55

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:04:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'None (None)'	Danyel Johnson (b) (4)	17 Nov 2020 20:00:55

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:04:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'None (None)'	Danyel Johnson (b) (4)	17 Nov 2020 20:00:55

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:04:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'None (None)'	Danyel Johnson (b) (4)	17 Nov 2020 20:00:55

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:04:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'None (None)'	Danyel Johnson (b) (4)	17 Nov 2020 20:00:55

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:04:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'None (None)'	Danyel Johnson (b) (4)	17 Nov 2020 20:00:55

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:04:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'None (None)'	Danyel Johnson (b) (4)	17 Nov 2020 20:00:55

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:04:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'None (None)'	Danyel Johnson (b) (4)	17 Nov 2020 20:00:55

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:04:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Mild (Mild)'	Danyel Johnson (b) (4)	17 Nov 2020 20:00:55

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:04:59

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Response noted as " UPDATED", however the initiated Illness visit folder is still blank and not reflecting with corresponding SARS-CoV-2 serum sample dated 16 NOV 2020, please verify and update the data as needed, or provide clarification. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Dec 2020 11:28:13
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Response noted as " UPDATED", however the initiated Illness visit folder is still blank and not reflecting with corresponding SARS-CoV-2 serum sample dated 16 NOV 2020, please verify and update the data as needed, or provide clarification. Thank you. ' answered with 'Completed' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	16 Dec 2020 00:06:31
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Response noted as " UPDATED", however the initiated Illness visit folder is still blank and not reflecting with corresponding SARS-CoV-2 serum sample dated 16 NOV 2020, please verify and update the data as needed, or provide clarification. Thank you. ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 10:56:07
User closed query 'Per GCL Lab Reconciliation-Re-Query : SARS-CoV-2 serum sample: Thank you for your response, as it now confirmed that the SARS-COV-2 serum sample has been collected and results received, Please kindly update the details of SARS-CoV-2 serum sample dated 16 NOV 2020 in Illness visit folder under SARS-CoV-2 serum sample collection form with date and other details accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 10:56:07

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Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:04:59

[Date of Visit](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation-Re-Query : SARS-CoV-2 serum sample: Thank you for your response, as it now confirmed that the SARS-COV-2 serum sample has been collected and results received, Please kindly update the details of SARS-CoV-2 serum sample dated 16 NOV 2020 in Illness visit folder under SARS-CoV-2 serum sample collection form with date and other details accordingly. Thank you.'	Danyel Johnson (b) (4)	14 Dec 2020 14:01:14
answered with 'UPDATED' (Site from DM). User opened query 'Per GCL Lab Reconciliation-Re-Query : SARS-CoV-2 serum sample: Thank you for your response, as it now confirmed that the SARS-COV-2 serum sample has been collected and results received, Please kindly update the details of SARS-CoV-2 serum sample dated 16 NOV 2020 in Illness visit folder under SARS-CoV-2 serum sample collection form with date and other details accordingly. Thank you.'	(b) (4), (b) (6)	09 Dec 2020 06:52:23
(Site from DM).		
Query 'Per GCL Lab Reconciliation-Re-Query : SARS-CoV-2 serum sample: Thank you for your response, as it now confirmed that the SARS-COV-2 serum samples have been collected and results recieved, Please kindly update the details by creating Illness visit folder,and updating under appropriate visit as EDC has provision to record SARS-CoV-2 serum samples in Illness visit folder only under SARS-CoV-2 serum sample collection form. Thank you.'	(b) (4), (b) (6)	09 Dec 2020 06:49:45
canceled (Site from DM).		
User opened query 'Per GCL Lab Reconciliation-Re-Query : SARS-CoV-2 serum sample: Thank you for your response, as it now confirmed that the SARS-COV-2 serum samples have been collected and results recieved, Please kindly update the details by creating Illness visit folder,and updating under appropriate visit as EDC has provision to record SARS-CoV-2 serum samples in Illness visit folder only under SARS-CoV-2 serum sample collection form. Thank you.'	(b) (4), (b) (6)	09 Dec 2020 06:49:38
(Site from DM).		

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Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:04:59

[Date of Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 16 NOV 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit or provide clarification, thank you.' (Site from DM). Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 16 NOV 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit or provide clarification, thank you.' answered with 'Samples have been sent and results received ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 06:49:38
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 16 NOV 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit or provide clarification, thank you.' (Site from DM).	Danyel Johnson (b) (4)	08 Dec 2020 01:34:22
User entered '16 Nov 2020'	(b) (4), (b) (6)	26 Nov 2020 09:28:55
	Danyel Johnson (b) (4)	17 Nov 2020 20:02:09

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:04:59

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	17 Nov 2020 20:02:09

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:04:59

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User closed query 'Per CDM: Site response is noted as 'pending results'. Please respond when results are in and updated. Thank you.' (Site from DM).	(b) (4)	
Query 'Per CDM: Site response is noted as 'pending results'. Please respond when results are in and updated. Thank you.' answered with 'Verified and updated ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 09:48:56
Query 'Per CDM: Site response is noted as 'pending results'. Please respond when results are in and updated. Thank you.' answered with 'Verified and updated ' (Site from DM).	Danyel Johnson (b) (4)	08 Dec 2020 01:35:50
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	08 Dec 2020 01:33:14
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	20 Nov 2020 18:10:05
User opened query 'Per CDM: Site response is noted as 'pending results'. Please respond when results are in and updated. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 18:10:01
Query 'Data is required. Please complete.' answered with 'Pending results' (Site from System).	Danyel Johnson (b) (4)	18 Nov 2020 21:37:32
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	17 Nov 2020 20:02:09
	Danyel Johnson (b) (4)	17 Nov 2020 20:02:09
	(b) (4)	

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:04:59

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '16 Nov 2020'	Danyel Johnson (b) (4)	17 Nov 2020 20:02:09

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:04:59

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Danyel Johnson (b) (4)	17 Nov 2020 20:02:09

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:04:59

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered empty.	Danyel Johnson (b) (4)	17 Nov 2020 20:02:09

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:04:59

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)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User closed query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	System	14 Dec 2020 18:18:21
User opened query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	System	14 Dec 2020 18:17:56
User entered 'No (N)'	Danyel Johnson (b) (4)	17 Nov 2020 20:02:09

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:04:59

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered empty.	Danyel Johnson (b) (4)	17 Nov 2020 20:02:09

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:04:59

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User closed query 'please complete the next page "generate next C-19 Assessment. Per source, no. please confirm and update.' (Site from CRA).	(b) (4)	22 Dec 2020 17:18:05
Query 'please complete the next page "generate next C-19 Assessment. Per source, no. please confirm and update.' answered with 'Completed' (Site from CRA).	Danyel Johnson (b) (4)	14 Dec 2020 18:19:00
User entered empty; reason for change Data Entry Error	Danyel Johnson (b) (4)	14 Dec 2020 18:18:21
User entered 'No (N)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	14 Dec 2020 18:17:56
User opened query 'please complete the next page "generate next C-19 Assessment. Per source, no. please confirm and update.' (Site from CRA).	(b) (4), (b) (6)	14 Dec 2020 18:16:39
User entered empty.	Danyel Johnson (b) (4)	17 Nov 2020 20:02:09

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:04:59

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User entered '0'	System	08 Dec 2020 01:33:14

US3832150

Folder: Covid-19 Assessment 16 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 10:04:59

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'No (N)'	Danyel Johnson (b) (4)	14 Dec 2020 18:18:52

US3832150

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 10:04:59

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:22
User accepted default value 'Day 3 (Day 3)'	Danyel Johnson (b) (4) (b) (4)	16 Dec 2020 00:04:51

US3832150

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 10:04:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:22
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 22NOV2020 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). User signature succeeded.	(b) (4), (b) (6) Gowdhami Mohan (b) (4)	29 Apr 2021 07:25:52 29 Apr 2021 02:21:24
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 22NOV2020 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 'Updated per review' (Site from DM). Signature has been broken.	Danyel Johnson (b) (4) Danyel Johnson (b) (4)	28 Apr 2021 12:24:19 28 Apr 2021 12:23:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	28 Apr 2021 12:23:09
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 22NOV2020 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). User signature succeeded.	(b) (4), (b) (6) Gowdhami Mohan (b) (4)	28 Apr 2021 04:23:11 21 Feb 2021 17:13:49
User entered 'NA (COVID-19 Negative) (NA)'	Danyel Johnson (b) (4)	16 Dec 2020 00:04:51

US3832150

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 10:04:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:22
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
Signature has been broken.	Danyel Johnson (b) (4)	28 Apr 2021 12:23:09
User entered '18 Nov 2020' reason for change: Data Entry Error	Danyel Johnson (b) (4)	28 Apr 2021 12:23:09
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered empty.	Danyel Johnson (b) (4)	16 Dec 2020 00:04:51

US3832150

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 10:04:59

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:22
User accepted default value 'Day 5 (Day 5)'	Danyel Johnson (b) (4) (b) (4)	16 Dec 2020 00:04:51

US3832150

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 10:04:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:22
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 24NOV2020 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). User signature succeeded.	(b) (4), (b) (6) Gowdhami Mohan (b) (4)	29 Apr 2021 07:26:00 29 Apr 2021 02:21:24
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 24NOV2020 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 'Site will contact PPD to update collection date' (Site from DM). Signature has been broken.	Danyel Johnson (b) (4) Danyel Johnson (b) (4)	28 Apr 2021 12:32:39 28 Apr 2021 12:30:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	28 Apr 2021 12:30:01
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 24NOV2020 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). User signature succeeded.	(b) (4), (b) (6) Gowdhami Mohan (b) (4)	28 Apr 2021 04:23:44 21 Feb 2021 17:13:49
User entered 'NA (COVID-19 Negative) (NA)'	Danyel Johnson (b) (4)	16 Dec 2020 00:04:51

US3832150

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 10:04:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:22
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
Signature has been broken.	Danyel Johnson (b) (4)	28 Apr 2021 12:30:01
User entered '20 Nov 2020' reason for change: Data Entry Error	Danyel Johnson (b) (4)	28 Apr 2021 12:30:01
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered empty.	Danyel Johnson (b) (4)	16 Dec 2020 00:04:51

US3832150

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 10:04:59

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:22
User accepted default value 'Day 7 (Day 7)'	Danyel Johnson (b) (4) (b) (4)	16 Dec 2020 00:04:51

US3832150

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 10:04:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:22
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'NA (COVID-19 Negative) (NA)'	Danyel Johnson (b) (4)	16 Dec 2020 00:04:51

US3832150

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 10:04:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:22
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered empty.	Danyel Johnson (b) (4)	16 Dec 2020 00:04:51

US3832150

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 10:04:59

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:22
User accepted default value 'Day 9 (Day 9)'	Danyel Johnson (b) (4) (b) (4)	16 Dec 2020 00:04:51

US3832150

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 10:04:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:22
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'NA (COVID-19 Negative) (NA)'	Danyel Johnson (b) (4)	16 Dec 2020 00:04:51

US3832150

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 10:04:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:22
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered empty.	Danyel Johnson (b) (4)	16 Dec 2020 00:04:51

US3832150

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 10:04:59

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:22
User accepted default value 'Day 14 (Day 14)'	Danyel Johnson (b) (4) (b) (4)	16 Dec 2020 00:04:51

US3832150

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 10:04:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:22
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'NA (COVID-19 Negative) (NA)'	Danyel Johnson (b) (4)	16 Dec 2020 00:04:51

US3832150

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 10:04:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:22
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered empty.	Danyel Johnson (b) (4)	16 Dec 2020 00:04:51

US3832150

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 10:04:59

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:22
User accepted default value 'Day 21 (Day 21)'	Danyel Johnson (b) (4) (b) (4)	16 Dec 2020 00:04:51

US3832150

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 10:04:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:22
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'NA (COVID-19 Negative) (NA)'	Danyel Johnson (b) (4)	16 Dec 2020 00:04:51

US3832150

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 10:04:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:22
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered empty.	Danyel Johnson (b) (4)	16 Dec 2020 00:04:51

US3832150

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 10:04:59

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:22
User accepted default value 'Day 28 (Day 28)'	Danyel Johnson (b) (4) (b) (4)	16 Dec 2020 00:04:51

US3832150

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 10:04:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:22
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'NA (COVID-19 Negative) (NA)'	Danyel Johnson (b) (4)	16 Dec 2020 00:04:51

US3832150

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 10:04:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:22
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered empty.	Danyel Johnson (b) (4)	16 Dec 2020 00:04:51

US3832150

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:19:43
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	16 Dec 2020 00:02:05

US3832150

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:59

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:19:43
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '16 Nov 2020'	Danyel Johnson (b) (4)	16 Dec 2020 00:02:05

US3832150

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:59

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:19:43
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Clinic (Clinic)'	Danyel Johnson (b) (4)	16 Dec 2020 00:02:05

US3832150

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:19:43
User entered 'SICKD1'	System	16 Dec 2020 00:02:05

US3832150

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:19:53
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	16 Dec 2020 00:03:10

US3832150

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:19:53
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '16 Nov 2020'	Danyel Johnson (b) (4)	16 Dec 2020 00:03:10

US3832150

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:19:53
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '11:36'	Danyel Johnson (b) (4)	16 Dec 2020 00:03:10

US3832150

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:19:53
User entered '16 Nov 2020 11:36'	System	16 Dec 2020 00:03:10

US3832150

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:19:53
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '163.8' cm	(b) (4) Danyel Johnson (b) (4)	16 Dec 2020 00:03:10
DataPoint set to visible.	(b) (4) System	16 Dec 2020 00:02:05

US3832150

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:19:53
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '58.4' kg	Danyel Johnson (b) (4)	16 Dec 2020 00:03:10
DataPoint set to visible.	System	16 Dec 2020 00:02:05

US3832150

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:19:53
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '97.0' F	Danyel Johnson (b) (4)	16 Dec 2020 00:03:10

US3832150

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:19:53
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Oral (Oral)'	Danyel Johnson (b) (4)	16 Dec 2020 00:03:10

US3832150

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:19:53
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered empty.	Danyel Johnson (b) (4)	16 Dec 2020 00:03:10

US3832150

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:19:53
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '82'	Danyel Johnson (b) (4)	16 Dec 2020 00:03:10

US3832150

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:19:53
User entered 'bpm'	System	16 Dec 2020 00:03:10

US3832150

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:19:53
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '14'	Danyel Johnson (b) (4)	16 Dec 2020 00:03:10

US3832150

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:19:53
User entered 'breaths/min'	System	16 Dec 2020 00:03:10

US3832150

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:19:53
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '108'	Danyel Johnson (b) (4)	16 Dec 2020 00:03:10

US3832150

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:19:53
User entered 'mmHg'	System	16 Dec 2020 00:03:10

US3832150

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:19:53
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '68'	Danyel Johnson (b) (4)	16 Dec 2020 00:03:10

US3832150

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:19:53
User entered 'mmHg'	System	16 Dec 2020 00:03:10

US3832150

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:19:53

US3832150

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:19:53

US3832150

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:04:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	16 Dec 2020 00:03:25

US3832150

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:04:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '16 Nov 2020'	Danyel Johnson (b) (4)	16 Dec 2020 00:03:25

US3832150

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 10:04:59

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:10
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	16 Dec 2020 00:03:42

US3832150

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 10:04:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:10
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '16 Nov 2020'	Danyel Johnson (b) (4)	16 Dec 2020 00:03:42

US3832150

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'No (N)'	Danyel Johnson (b) (4)	16 Dec 2020 00:05:06
	(b) (4)	

US3832150

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:59

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	16 Dec 2020 00:05:06
	(b) (4)	

US3832150

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:59

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	16 Dec 2020 00:05:06
	(b) (4)	

US3832150

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:59

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	16 Dec 2020 00:05:06

US3832150

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'No (N)'	Danyel Johnson (b) (4)	16 Dec 2020 00:05:37
	(b) (4)	

US3832150

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	16 Dec 2020 00:05:37
	(b) (4)	

US3832150

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	16 Dec 2020 00:05:37
	(b) (4)	

US3832150

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Dec 2020 00:05:37

US3832150

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	16 Dec 2020 00:05:37
	(b) (4)	

US3832150

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	16 Dec 2020 00:05:37
	(b) (4)	

US3832150

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	16 Dec 2020 00:05:37
	(b) (4)	

US3832150

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	16 Dec 2020 00:05:37
	(b) (4)	

US3832150

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Dec 2020 00:05:37

US3832150

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	16 Dec 2020 00:05:37
	(b) (4)	

US3832150

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Dec 2020 00:05:37

US3832150

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	16 Dec 2020 00:05:37
	(b) (4)	

US3832150

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Dec 2020 00:05:37

US3832150

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered empty.	(b) (4) Danyel Johnson (b) (4)	16 Dec 2020 00:05:37
	(b) (4)	

US3832150

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Dec 2020 00:05:37

US3832150

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:04:59

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Dec 2020 00:05:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Dec 2020 00:05:27
User entered 'No (N)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	16 Dec 2020 00:05:27
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Dec 2020 00:05:22
User entered empty.	Danyel Johnson (b) (4)	16 Dec 2020 00:05:22
	(b) (4)	

US3832150

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:04:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	16 Dec 2020 00:05:22
	(b) (4)	

US3832150

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 10:04:59

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	16 Dec 2020 00:05:48

US3832150

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 10:04:59

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	16 Dec 2020 00:05:48
	(b) (4)	

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Yes (Y)'	Emma Partin (b) (4)	13 Jan 2021 13:13:44

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:59

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '13 Jan 2021'	Emma Partin (b) (4)	13 Jan 2021 13:13:44

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:59

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Clinic (Clinic)'	Emma Partin (b) (4)	13 Jan 2021 13:13:44

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User entered 'UNBLND_DECIDE'	System	13 Jan 2021 13:13:44

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:04:59

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '13 Jan 2021'	Emma Partin (b) (4)	13 Jan 2021 13:14:58

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:04:59

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
User entered '0'	Rodolfo Barrera (b) (4)	08 Apr 2021 12:46:26
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:08:03

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:04:59

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Yes (Y)'	Emma Partin (b) (4)	13 Jan 2021 13:14:58

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:04:59

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User closed query 'Per CDM, per Sponsor Review: IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 02:01:49
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
Query 'Per CDM, per Sponsor Review: IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'Updated.' (Site from DM).	Rodolfo Barrera (b) (4)	08 Apr 2021 12:46:36
User entered 'Amendment 6 or later (Amendment 6 or later)'	Rodolfo Barrera (b) (4)	08 Apr 2021 12:46:26
User opened query 'Per CDM, per Sponsor Review: IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 10:27:34
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:08:03

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:04:59

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '13 Jan 2021'	Emma Partin (b) (4)	13 Jan 2021 13:14:58

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:04:59

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Placebo (Placebo)'	Emma Partin (b) (4)	13 Jan 2021 13:14:58

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:04:59

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 06:52:41
User entered 'Placebo (Placebo)'	Emma Partin (b) (4)	13 Jan 2021 13:14:58
	(b) (4)	

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:04:59

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 06:52:41
User entered 'Placebo (Placebo)'	Emma Partin (b) (4)	13 Jan 2021 13:14:58
	(b) (4)	

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:04:59

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Yes (Y)'	Emma Partin (b) (4)	13 Jan 2021 13:14:58

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:04:59

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User entered '1'	System	13 Jan 2021 13:14:58

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:04:59

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User entered 'I'	System	13 Jan 2021 13:14:58

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:04:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '64.5' in	Emma Partin (b) (4)	13 Jan 2021 14:08:12

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:04:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '126.8' lb	Emma Partin (b) (4)	13 Jan 2021 14:08:12

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:04:59

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User entered '21.47384'	System	13 Jan 2021 14:08:12
DataPoint set to visible.	System	13 Jan 2021 13:14:58

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:04:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '64.5' in	Emma Partin (b) (4)	13 Jan 2021 14:08:12

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:04:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '126.8' lb	Emma Partin (b) (4)	13 Jan 2021 14:08:12

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:04:59

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User entered '21.47384'	System	13 Jan 2021 14:08:12
DataPoint set to visible.	System	13 Jan 2021 13:14:58

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User accepted default value 'Pre-Dose (PREDOSE)'	Emma Partin (b) (4) (b) (4)	13 Jan 2021 14:08:12

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Yes (Y)'	Emma Partin (b) (4)	13 Jan 2021 14:08:12

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '13 Jan 2021'	Emma Partin (b) (4)	13 Jan 2021 14:08:12

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '08:06'	Emma Partin (b) (4)	13 Jan 2021 14:08:12

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User entered '13 Jan 2021 08:06'	System	13 Jan 2021 14:08:12

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '97.0' F	Emma Partin (b) (4)	13 Jan 2021 14:08:12

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Oral (Oral)'	Emma Partin (b) (4)	13 Jan 2021 14:08:12

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered empty.	Emma Partin (b) (4)	13 Jan 2021 14:08:12

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '88'	Emma Partin (b) (4)	13 Jan 2021 14:08:12

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User entered 'bpm'	System	13 Jan 2021 14:08:12

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '12'	Emma Partin (b) (4)	13 Jan 2021 14:08:12

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User entered 'breaths/min'	System	13 Jan 2021 14:08:12

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '106'	Emma Partin (b) (4)	13 Jan 2021 14:08:12

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User entered 'mmHg'	System	13 Jan 2021 14:08:12

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '60'	Emma Partin (b) (4)	13 Jan 2021 14:08:12

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User entered 'mmHg'	System	13 Jan 2021 14:08:12

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:04:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '64.5' in	Emma Partin (b) (4)	13 Jan 2021 14:08:12

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:04:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '126.8' lb	Emma Partin (b) (4)	13 Jan 2021 14:08:12

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:04:59

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User entered '21.47384'	System	13 Jan 2021 14:08:12
DataPoint set to visible.	System	13 Jan 2021 13:14:58

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User accepted default value 'Post-Dose (POSTDOSE)'	Emma Partin (b) (4) (b) (4)	13 Jan 2021 14:08:12

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Yes (Y)'	Emma Partin (b) (4)	13 Jan 2021 14:08:12

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '13 Jan 2021'	Emma Partin (b) (4)	13 Jan 2021 14:08:12

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '08:55'	Emma Partin (b) (4)	13 Jan 2021 14:08:12

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User entered '13 Jan 2021 08:55'	System	13 Jan 2021 14:08:12

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '97.8' F reason for change: Data Entry Error	Danyel Johnson (b) (4)	17 Feb 2021 18:51:04
User entered '97.08' F	Emma Partin (b) (4)	13 Jan 2021 14:08:12

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Oral (Oral)'	Emma Partin (b) (4)	13 Jan 2021 14:08:12

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered empty.	Emma Partin (b) (4)	13 Jan 2021 14:08:12

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '73'	Emma Partin (b) (4)	13 Jan 2021 14:08:12

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User entered 'bpm'	System	13 Jan 2021 14:08:12

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '12'	Emma Partin (b) (4)	13 Jan 2021 14:08:12

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User entered 'breaths/min'	System	13 Jan 2021 14:08:12

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '109'	Emma Partin (b) (4)	13 Jan 2021 14:08:12

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User entered 'mmHg'	System	13 Jan 2021 14:08:12

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '72'	Emma Partin (b) (4)	13 Jan 2021 14:08:12

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User entered 'mmHg'	System	13 Jan 2021 14:08:12

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:04:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Yes (Y)'	Emma Partin (b) (4)	13 Jan 2021 13:15:06

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:04:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '13 Jan 2021'	Emma Partin (b) (4)	13 Jan 2021 13:15:06

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Yes (Y)'	Emma Partin (b) (4)	13 Jan 2021 14:05:45

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:59

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered empty.	Emma Partin (b) (4)	13 Jan 2021 14:05:45

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:59

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)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered empty.	Emma Partin (b) (4)	13 Jan 2021 14:05:45

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:59

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User entered 'mRNA-1273'	System	13 Jan 2021 14:05:45
DataPoint set to visible.	System	13 Jan 2021 13:14:58

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '13 Jan 2021'	Emma Partin (b) (4)	13 Jan 2021 14:05:45

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:59

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '08:24'	Emma Partin (b) (4)	13 Jan 2021 14:05:45

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:59

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User entered '13 Jan 2021 08:24'	System	13 Jan 2021 14:05:45

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:59

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Left Arm (LEFT ARM)'	Emma Partin (b) (4)	13 Jan 2021 14:05:45

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:59

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User entered 'ONCE'	System	13 Jan 2021 14:05:45

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:59

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User entered 'INTRAMUSCULAR'	System	13 Jan 2021 14:05:45

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Yes (Y)'	Emma Partin (b) (4)	13 Jan 2021 13:14:18

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '13 Jan 2021'	Emma Partin (b) (4)	13 Jan 2021 13:14:18

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:59

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '08:02'	Emma Partin (b) (4)	13 Jan 2021 13:14:18

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User entered '13 Jan 2021 08:02'	System	13 Jan 2021 13:14:18

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:04:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Yes (Y)'	Emma Partin (b) (4)	13 Jan 2021 13:14:32

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:04:59

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '13 Jan 2021'	Emma Partin (b) (4)	13 Jan 2021 13:14:32

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:04:59

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '07:58'	Emma Partin (b) (4)	13 Jan 2021 13:14:32

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:04:59

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User entered '13 Jan 2021 07:58'	System	13 Jan 2021 13:14:32

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Yes (Y)'	Emma Partin (b) (4)	13 Jan 2021 13:15:13

US3832150

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:49:28
User entered 'I'	System	13 Jan 2021 13:15:13

US3832150

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:34:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	21 Jan 2021 19:56:48
	(b) (4)	

US3832150

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:34:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User closed query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	19 Feb 2021 15:56:17
Query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	19 Feb 2021 15:56:17
User entered '21 Jan 2021' reason for change: Data Entry Error	Danyel Johnson (b) (4)	19 Feb 2021 15:56:17
	(b) (4)	
User opened query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	17 Feb 2021 19:20:41
User entered '13 Jan 2021' reason for change: Data Entry Error	Danyel Johnson (b) (4)	17 Feb 2021 19:20:41
	(b) (4)	
User entered '21 Jan 2021'	Rodolfo Barrera (b) (4)	21 Jan 2021 19:56:48
	(b) (4)	

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Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:34:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Rodolfo Barrera (b) (4)	21 Jan 2021 19:56:48
	(b) (4)	

US3832150

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:34:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered empty.	Rodolfo Barrera (b) (4)	21 Jan 2021 19:56:48
	(b) (4)	

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Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:34:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	21 Jan 2021 19:56:53
	(b) (4)	

US3832150

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:34:49
User entered 'I'	System	21 Jan 2021 19:56:53

US3832150

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:59

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:34:49
User entered 'I'	System	21 Jan 2021 19:56:53
DataPoint set to visible.	System	21 Jan 2021 19:56:53

US3832150

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Yes (Y)'	(b) (4) Emma Partin (b) (4)	10 Feb 2021 21:37:23

US3832150

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:59

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '10 Feb 2021'	(b) (4) Emma Partin (b) (4)	10 Feb 2021 21:37:23

US3832150

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:59

[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 03:29:01
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Clinic (Clinic)'	Emma Partin (b) (4)	10 Feb 2021 21:37:23

US3832150

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User entered 'OLD29'	System	10 Feb 2021 21:37:23

US3832150

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User accepted default value 'Pre-Dose (PREDOSE)'	Emma Partin (b) (4) (b) (4)	10 Feb 2021 21:39:13

US3832150

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Yes (Y)'	(b) (4) Emma Partin (b) (4)	10 Feb 2021 21:39:13

US3832150

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '10 Feb 2021'	(b) (4) Emma Partin (b) (4)	10 Feb 2021 21:39:13

US3832150

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '12:09'	(b) (4) Emma Partin (b) (4)	10 Feb 2021 21:39:13

US3832150

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User entered '10 Feb 2021 12:09'	System	10 Feb 2021 21:39:13

US3832150

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '97.8' F	Emma Partin (b) (4)	10 Feb 2021 21:39:13

US3832150

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Oral (Oral)'	(b) (4) Emma Partin (b) (4)	10 Feb 2021 21:39:13

US3832150

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered empty.	Emma Partin (b) (4)	10 Feb 2021 21:39:13

US3832150

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '72'	Emma Partin (b) (4)	10 Feb 2021 21:39:13

US3832150

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User entered 'bpm'	System	10 Feb 2021 21:39:13

US3832150

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '14'	Emma Partin (b) (4)	10 Feb 2021 21:39:13

US3832150

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User entered 'breaths/min'	System	10 Feb 2021 21:39:13

US3832150

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '107'	(b) (4) Emma Partin (b) (4)	10 Feb 2021 21:39:13

US3832150

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User entered 'mmHg'	System	10 Feb 2021 21:39:13

US3832150

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '75'	(b) (4) Emma Partin (b) (4)	10 Feb 2021 21:39:13

US3832150

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User entered 'mmHg'	System	10 Feb 2021 21:39:13

US3832150

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User accepted default value 'Post-Dose (POSTDOSE)'	Emma Partin (b) (4) (b) (4)	10 Feb 2021 21:39:13

US3832150

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Yes (Y)'	Emma Partin (b) (4)	10 Feb 2021 21:39:13

US3832150

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '10 Feb 2021'	(b) (4) Emma Partin (b) (4)	10 Feb 2021 21:39:13

US3832150

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '12:52'	(b) (4) Emma Partin (b) (4)	10 Feb 2021 21:39:13

US3832150

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User entered '10 Feb 2021 12:52'	System	10 Feb 2021 21:39:13

US3832150

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '97.8' F	Emma Partin (b) (4)	10 Feb 2021 21:39:13

US3832150

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Oral (Oral)'	(b) (4) Emma Partin (b) (4)	10 Feb 2021 21:39:13

US3832150

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered empty.	(b) (4) Emma Partin (b) (4)	10 Feb 2021 21:39:13

US3832150

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '72'	Emma Partin (b) (4)	10 Feb 2021 21:39:13

US3832150

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User entered 'bpm'	System	10 Feb 2021 21:39:13

US3832150

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '14'	Emma Partin (b) (4)	10 Feb 2021 21:39:13

US3832150

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User entered 'breaths/min'	System	10 Feb 2021 21:39:13

US3832150

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '127'	(b) (4) Emma Partin (b) (4)	10 Feb 2021 21:39:13

US3832150

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User entered 'mmHg'	System	10 Feb 2021 21:39:13

US3832150

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '78'	Emma Partin (b) (4)	10 Feb 2021 21:39:13

US3832150

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User entered 'mmHg'	System	10 Feb 2021 21:39:13

US3832150

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:04:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Yes (Y)'	Emma Partin (b) (4)	10 Feb 2021 21:37:32

US3832150

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:04:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '10 Feb 2021'	(b) (4) Emma Partin (b) (4)	10 Feb 2021 21:37:32

US3832150

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Yes (Y)'	Emma Partin (b) (4)	10 Feb 2021 21:37:49

US3832150

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:59

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered empty.	(b) (4) Emma Partin (b) (4)	10 Feb 2021 21:37:49

US3832150

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:59

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)	01 May 2021 03:29:01
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered empty.	Emma Partin (b) (4)	10 Feb 2021 21:37:49

US3832150

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:59

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User entered 'mRNA-1273'	System	10 Feb 2021 21:37:49
DataPoint set to visible.	System	21 Jan 2021 19:56:53

US3832150

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:59

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '10 Feb 2021'	(b) (4) Emma Partin (b) (4)	10 Feb 2021 21:37:49

US3832150

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:59

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '12:19'	Emma Partin (b) (4)	10 Feb 2021 21:37:49

US3832150

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:59

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User entered '10 Feb 2021 12:19'	System	10 Feb 2021 21:37:49

US3832150

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:59

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Left Arm (LEFT ARM)'	Emma Partin (b) (4)	10 Feb 2021 21:37:49

US3832150

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:59

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User entered 'ONCE'	System	10 Feb 2021 21:37:49

US3832150

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:59

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User entered 'INTRAMUSCULAR'	System	10 Feb 2021 21:37:49

US3832150

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Yes (Y)'	Emma Partin (b) (4)	10 Feb 2021 21:38:01

US3832150

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:29:01
User entered 'I'	System	10 Feb 2021 21:38:01

US3832150

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	17 Feb 2021 15:05:55

US3832150

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '17 Feb 2021'	Rodolfo Barrera (b) (4)	17 Feb 2021 15:05:55

US3832150

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Contact Made (CONTACT MADE)'	Rodolfo Barrera (b) (4)	17 Feb 2021 15:05:55

US3832150

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered empty.	Rodolfo Barrera (b) (4)	17 Feb 2021 15:05:55

US3832150

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	17 Feb 2021 15:05:58

US3832150

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:24
User entered 'I'	System	17 Feb 2021 15:05:58

US3832150

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:48:44
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	16 Mar 2021 18:19:45

US3832150

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:59

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:48:44
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
User entered '11 Mar 2021'	Rodolfo Barrera (b) (4)	16 Mar 2021 18:19:45

US3832150

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:59

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:48:44
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
User entered 'Clinic (Clinic)'	Rodolfo Barrera (b) (4)	16 Mar 2021 18:19:45

US3832150

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:48:44
User entered 'OLD57'	System	16 Mar 2021 18:19:45

US3832150

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:48:44
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
User entered 'No (N)'	Rodolfo Barrera (b) (4)	16 Mar 2021 18:19:51

US3832150

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:48:44
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
User entered empty.	Rodolfo Barrera (b) (4)	16 Mar 2021 18:19:51

US3832150

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:48:44
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
User entered empty.	Rodolfo Barrera (b) (4)	16 Mar 2021 18:19:51

US3832150

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:48:44
User entered empty.	System	16 Mar 2021 18:19:51

US3832150

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:48:44
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
User entered empty.	Rodolfo Barrera (b) (4)	16 Mar 2021 18:19:51

US3832150

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:48:44
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
User entered empty.	Rodolfo Barrera (b) (4)	16 Mar 2021 18:19:51

US3832150

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:48:44
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
User entered empty.	Rodolfo Barrera (b) (4)	16 Mar 2021 18:19:51

US3832150

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:48:44
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
User entered empty.	Rodolfo Barrera (b) (4)	16 Mar 2021 18:19:51

US3832150

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:48:44
User entered empty.	System	16 Mar 2021 18:19:51

US3832150

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:48:44
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
User entered empty.	Rodolfo Barrera (b) (4)	16 Mar 2021 18:19:51

US3832150

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:48:44
User entered empty.	System	16 Mar 2021 18:19:51

US3832150

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:48:44
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
User entered empty.	Rodolfo Barrera (b) (4)	16 Mar 2021 18:19:51

US3832150

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:48:44
User entered empty.	System	16 Mar 2021 18:19:51

US3832150

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:48:44
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
User entered empty.	Rodolfo Barrera (b) (4)	16 Mar 2021 18:19:51

US3832150

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:48:44
User entered empty.	System	16 Mar 2021 18:19:51

US3832150

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:48:44

US3832150

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:59

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:48:44

US3832150

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:04:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:48:44
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
User entered 'No (N)'	Rodolfo Barrera (b) (4)	16 Mar 2021 18:19:59

US3832150

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:04:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:48:44
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
User entered empty.	Rodolfo Barrera (b) (4)	16 Mar 2021 18:19:59

US3832150

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:48:44
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	16 Mar 2021 18:20:16

US3832150

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:48:44
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
User entered '11 Mar 2021'	Rodolfo Barrera (b) (4)	16 Mar 2021 18:20:16

US3832150

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:59

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:48:44
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
User entered '13:26'	Rodolfo Barrera (b) (4)	16 Mar 2021 18:20:16

US3832150

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:48:44
User entered '11 Mar 2021 13:26'	System	16 Mar 2021 18:20:16

US3832150

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:04:59

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:51
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Danyel Johnson (b) (4)	29 Jan 2021 16:06:46
User entered 'No (N)'	(b) (4)	
	Danyel Johnson (b) (4)	13 Jan 2021 00:28:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:59

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:23:50
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:43:36
Un-reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:43:34
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:57:10
User entered	System	01 Feb 2021 15:57:05
'USA-US100-2021-mRNA-1273-P301000008'		
User entered 'New'	(b) (4), (b) (6)	01 Feb 2021 15:57:05

US3832150

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:59

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 13:32:49
User closed query 'Per source the AE is titled as "Uterine Cancer". Please review source and revise source or EDC, so that data can be verified.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 13:32:33
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female malignant and unspecified, HLT: Endometrial neoplasms malignant, PT: Endometrial cancer, LLT: Endometrial carcinoma - version MedDRA\23.0.	Coder Import (b) (4)	20 Apr 2021 21:44:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	20 Apr 2021 21:44:45
Query 'Per source the AE is titled as "Uterine Cancer". Please review source and revise source or EDC, so that data can be verified.' answered with 'Updated per review of medical records' (Site from CRA).	Danyel Johnson (b) (4)	20 Apr 2021 19:43:54
Data point term sent to Coder	System	20 Apr 2021 19:40:27
Coding entries removed.	Danyel Johnson (b) (4)	20 Apr 2021 19:39:37
User entered 'Endometrioid Carcinoma' reason for change: Data Entry Error	(b) (4)	
	Danyel Johnson (b) (4)	20 Apr 2021 19:39:37
User opened query 'Per source the AE is titled as "Uterine Cancer". Please review source and revise source or EDC, so that data can be verified.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 19:23:45
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female malignant and unspecified, HLT: Endometrial neoplasms malignant, PT: Endometrial cancer, LLT: Endometrial cancer - version MedDRA\23.0.	Coder Import (b) (4)	16 Feb 2021 15:07:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	16 Feb 2021 15:07:00
Data point term sent to Coder	System	16 Feb 2021 15:05:54
Coding entries removed.	Danyel Johnson (b) (4)	16 Feb 2021 15:05:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:59

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'Endometrial Cancer' reason for change: Data Entry Error	Danyel Johnson (b) (4)	16 Feb 2021 15:05:50
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female malignant and unspecified, HLT: Uterine neoplasms malignant NEC, PT: Uterine cancer, LLT: Uterine cancer - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 16:12:20
Data point term sent to Coder	(b) (4)	
User entered 'Uterine Cancer'	Coder Import (b) (4)	29 Jan 2021 16:12:20
	(b) (4)	
	System	29 Jan 2021 16:11:49
	Danyel Johnson (b) (4)	29 Jan 2021 16:11:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User closed query 'Please add hysterectomy listed in source under this AE into the Con Procedures Log.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:34:01
Query 'Please add hysterectomy listed in source under this AE into the Con Procedures Log.' answered with 'Log line #1 for concomitant procedures has hysterectomy noted' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	20 Apr 2021 19:36:07
User opened query 'Please add hysterectomy listed in source under this AE into the Con Procedures Log.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 19:25:48
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:23:57
User entered 'Yes (Y)'	Danyel Johnson (b) (4) (b) (4)	29 Jan 2021 16:11:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 19:26:18
User entered 'No (N)'	Danyel Johnson (b) (4)	29 Jan 2021 16:11:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 19:26:20
User entered 'No (N)'	Danyel Johnson (b) (4)	29 Jan 2021 16:11:24
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 13:34:32
User closed query 'Per source, start date 18Jan2021 , ongoing . Please verify the dates and update this form as needed. ' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 13:34:29
Query 'Per source, start date 18Jan2021 , ongoing . Please verify the dates and update this form as needed. ' answered with 'Source updated start date based on date endometrial biopsy was done' (Site from CRA).	Danyel Johnson (b) (4)	20 Apr 2021 19:42:19
	(b) (4)	
User opened query 'Per source, start date 18Jan2021 , ongoing . Please verify the dates and update this form as needed. ' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 20:14:57
Query 'Data entered is non-conformant. Please correct.' canceled (Site from System).	(b) (4), (b) (6)	07 Apr 2021 13:59:03
User closed query 'PV Query: Please correct the year in event start date (??-Oct-2021) and event end date (18-Jan-2020) as it is not conformant with the information provided in narrative.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 13:30:21
Query 'PV Query: Please correct the year in event start date (??-Oct-2021) and event end date (18-Jan-2020) as it is not conformant with the information provided in narrative.' answered with 'Corrected' (Site from Safety).	Danyel Johnson (b) (4)	24 Mar 2021 12:02:28
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	24 Mar 2021 12:00:53
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	24 Mar 2021 12:00:53
User entered 'UN Oct 2020' (non-conformant).	Danyel Johnson (b) (4)	24 Mar 2021 12:00:53
	(b) (4)	
User opened query 'PV Query: Please correct the year in event start date (??-Oct-2021) and event end date (18-Jan-2020) as it is not conformant with the information provided in narrative.' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 14:15:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: As per the narrative, the subject started experiencing symptoms of endometrial cancer (bleeding) in Oct 2020. However the start date of the event is 18 Jan 2021 when the pathology confirmed the endometrial cancer. Since the event start date should be the date when the subject experienced first sign and symptom, therefore please consider updating the event start date accordingly.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 20:13:40
Query 'PV Query: As per the narrative, the subject started experiencing symptoms of endometrial cancer (bleeding) in Oct 2020. However the start date of the event is 18 Jan 2021 when the pathology confirmed the endometrial cancer. Since the event start date should be the date when the subject experienced first sign and symptom, therefore please consider updating the event start date accordingly.' answered with 'updated' (Site from Safety).	Danyel Johnson (b) (4)	02 Mar 2021 13:25:57
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Mar 2021 13:25:49
User entered 'un Oct 2021' (non-conformant).	Danyel Johnson (b) (4)	02 Mar 2021 13:25:49
User opened query 'PV Query: As per the narrative, the subject started experiencing symptoms of endometrial cancer (bleeding) in Oct 2020. However the start date of the event is 18 Jan 2021 when the pathology confirmed the endometrial cancer. Since the event start date should be the date when the subject experienced first sign and symptom, therefore please consider updating the event start date accordingly.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 17:02:42
User entered '18 Jan 2021'	Danyel Johnson (b) (4)	29 Jan 2021 16:11:24

US3832150

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:59

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 13:34:38
User entered empty.	Danyel Johnson (b) (4)	29 Jan 2021 16:11:24
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 16:11:24

US3832150

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 13:34:50
User closed query 'Per source end date of AE is "Ongoing", Please review and revise your answer if needed.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 13:34:45
Query 'Per source end date of AE is "Ongoing", Please review and revise your answer if needed.' answered with 'Source corrected' (Site from CRA).	Danyel Johnson (b) (4)	20 Apr 2021 19:42:29
User opened query 'Per source end date of AE is "Ongoing", Please review and revise your answer if needed.' (Site from CRA).	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 19:33:19
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	16 Feb 2021 15:06:06
User entered 'No (N)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	16 Feb 2021 15:06:06
	(b) (4)	
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	16 Feb 2021 15:05:50
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	29 Jan 2021 16:11:24
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: The stop date of the event should be the date when the event recovered./treated. However, the stop date is reported as the date when the pathology confirmed endometrial cancer. Therefore, please consider updating the event end date accordingly. ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 19:40:44
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
Query 'PV Query: The stop date of the event should be the date when the event recovered./treated. However, the stop date is reported as the date when the pathology confirmed endometrial cancer. Therefore, please consider updating the event end date accordingly. ' answered with 'The date reported is the date of the Hysterectomy which ended the Endometroid Carcinoma' (Site from DM).	Danyel Johnson (b) (4)	26 Apr 2021 14:34:13
User opened query 'PV Query: The stop date of the event should be the date when the event recovered./treated. However, the stop date is reported as the date when the pathology confirmed endometrial cancer. Therefore, please consider updating the event end date accordingly. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 14:29:03
User closed query 'Per DM CLR: Please review and verify AE end date as it is prior to the start of this AE. Review and reconcile data as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 06:05:12
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:34:53
Query 'Per DM CLR: Please review and verify AE end date as it is prior to the start of this AE. Review and reconcile data as appropriate.' answered with 'Updated per review' (Site from DM).	Danyel Johnson (b) (4)	20 Apr 2021 19:44:08
User entered '18 Jan 2021' reason for change: Data Entry Error	Danyel Johnson (b) (4)	20 Apr 2021 19:43:00
User opened query 'Per DM CLR: Please review and verify AE end date as it is prior to the start of this AE. Review and reconcile data as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 13:04:50

US3832150

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: As per the narrative, the subject started experiencing symptoms of endometrial cancer (bleeding) in Oct 2020. However the start date of the event is 18 Jan 2021 when the pathology confirmed the endometrial cancer. Since the event start date should be the date when the subject experienced first sign and symptom, therefore please consider updating the event start date accordingly.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 20:13:43
Query 'PV Query: As per the narrative, the subject started experiencing symptoms of endometrial cancer (bleeding) in Oct 2020. However the start date of the event is 18 Jan 2021 when the pathology confirmed the endometrial cancer. Since the event start date should be the date when the subject experienced first sign and symptom, therefore please consider updating the event start date accordingly.' answered with 'UPdated' (Site from Safety).	Danyel Johnson (b) (4)	02 Mar 2021 13:26:05
User entered '18 Jan 2020' reason for change: Data Entry Error	(b) (4)	02 Mar 2021 13:25:49
User opened query 'PV Query: As per the narrative, the subject started experiencing symptoms of endometrial cancer (bleeding) in Oct 2020. However the start date of the event is 18 Jan 2021 when the pathology confirmed the endometrial cancer. Since the event start date should be the date when the subject experienced first sign and symptom, therefore please consider updating the event start date accordingly.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 17:02:59
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	16 Feb 2021 15:06:25
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	16 Feb 2021 15:06:25
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	16 Feb 2021 15:05:50

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Folder: Adverse Events

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '18 Jan 2021' reason for change: Data Entry Error	Danyel Johnson (b) (4)	16 Feb 2021 15:05:50
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 17:37:46
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'has not ended yet. Please close query until this has ended ' (Site from Safety).	Danyel Johnson (b) (4)	09 Feb 2021 18:48:26
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 14:51:24
User entered empty.	Danyel Johnson (b) (4)	29 Jan 2021 16:11:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:59

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 13:34:57
User entered empty.	Danyel Johnson (b) (4)	29 Jan 2021 16:11:24
	(b) (4)	

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Folder: Adverse Events

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: The stop date of the event should be the date when the event recovered./treated. However, the stop date is reported as the date when the pathology confirmed endometrial cancer. Therefore, please consider updating the event end date accordingly.' canceled (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 00:14:00
User opened query 'PV Query: The stop date of the event should be the date when the event recovered./treated. However, the stop date is reported as the date when the pathology confirmed endometrial cancer. Therefore, please consider updating the event end date accordingly.' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 14:13:10
User entered empty.	System	29 Jan 2021 16:11:24

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Folder: Adverse Events

Form: Adverse Events (1)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 20:15:18
User entered 'Grade 3/Severe (Grade 3/Severe)'	Danyel Johnson (b) (4) (b) (4)	29 Jan 2021 16:11:24

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Folder: Adverse Events

Form: Adverse Events (1)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 19:33:38
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	29 Jan 2021 16:11:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:59

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 19:33:48
User entered '0'	Danyel Johnson (b) (4)	29 Jan 2021 16:11:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 19:33:50
User entered '0'	Danyel Johnson (b) (4)	29 Jan 2021 16:11:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 19:33:52
User entered '0'	Danyel Johnson (b) (4)	29 Jan 2021 16:11:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:59

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 19:33:53
User entered empty.	Danyel Johnson (b) (4)	29 Jan 2021 16:11:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:59

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 19:33:55
User entered empty.	Danyel Johnson (b) (4)	29 Jan 2021 16:11:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 19:33:57
User entered empty.	Danyel Johnson (b) (4)	29 Jan 2021 16:11:24
	(b) (4)	

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Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 19:33:58
User entered empty.	Danyel Johnson (b) (4)	29 Jan 2021 16:11:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 19:34:00
User entered '0'	Danyel Johnson (b) (4)	29 Jan 2021 16:11:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 19:34:02
User entered '0'	Danyel Johnson (b) (4)	29 Jan 2021 16:11:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 19:34:04
User entered 'I'	Danyel Johnson (b) (4)	29 Jan 2021 16:11:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 20:15:35
User entered 'Not Related (NOT RELATED)'	Danyel Johnson (b) (4) (b) (4)	29 Jan 2021 16:11:24

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Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 20:15:37
User entered 'Not Related (NOT RELATED)'	Danyel Johnson (b) (4) (b) (4)	29 Jan 2021 16:11:24

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Form: Adverse Events (1)

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 20:15:39
User closed query 'PV Query: As the last dose of Placebo was given on 09 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 13:30:14
Query 'PV Query: As the last dose of Placebo was given on 09 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety).	Danyel Johnson (b) (4)	24 Mar 2021 12:02:45
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4)	24 Mar 2021 12:00:53
User opened query 'PV Query: As the last dose of Placebo was given on 09 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 14:16:36
User entered 'None (NONE)'	Danyel Johnson (b) (4)	29 Jan 2021 16:11:24
	(b) (4)	

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Form: Adverse Events (1)

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None

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 13:35:08
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Procedure recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 13:11:04
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Procedure recorded that matches this AE during this timeframe. Please review and update this field.' answered with 'Corrected' (Site from DM).	Danyel Johnson (b) (4)	24 Mar 2021 12:02:56
User entered '0' reason for change: Data Entry Error	(b) (4)	24 Mar 2021 12:00:53
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Procedure recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 05:59:33
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	09 Feb 2021 20:11:21
User entered '1' reason for change: Data Entry Error	Danyel Johnson (b) (4)	09 Feb 2021 20:11:21
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
User entered '0'	System	29 Jan 2021 16:11:24
	Danyel Johnson (b) (4)	29 Jan 2021 16:11:24
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 13:35:11
User entered '0'	Danyel Johnson (b) (4)	29 Jan 2021 16:11:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 13:35:13
User entered '1' reason for change: Data Entry Error	Danyel Johnson (b) (4)	24 Mar 2021 12:00:53
	(b) (4)	
User entered '0'	Danyel Johnson (b) (4)	29 Jan 2021 16:11:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 13:35:25
User closed query 'Per source outcome of AE is "Unknown". Please review source and revise if needed.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 13:35:22
Query 'Per source outcome of AE is "Unknown". Please review source and revise if needed.' answered with 'Updated per review' (Site from CRA).	Danyel Johnson (b) (4)	20 Apr 2021 19:44:20
User opened query 'Per source outcome of AE is "Unknown". Please review source and revise if needed.' (Site from CRA).	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 19:34:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Danyel Johnson (b) (4)	16 Feb 2021 15:06:25
Data Entry Error	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Danyel Johnson (b) (4)	16 Feb 2021 15:05:50
Data Entry Error	(b) (4)	
User closed query ' PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 17:37:53
Query ' PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' answered with 'Will be updated with medical records' (Site from Safety).	Danyel Johnson (b) (4)	09 Feb 2021 20:09:52
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	09 Feb 2021 18:53:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:59

[Outcome](#)

Audit	User	Time (GMT)
User opened query ' PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 14:51:55
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Jan 2021 16:11:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Jan 2021 16:11:45
User entered 'Unknown (UNKNOWN)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	29 Jan 2021 16:11:45
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Jan 2021 16:11:24
User entered empty.	Danyel Johnson (b) (4)	29 Jan 2021 16:11:24

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 13:35:31
User entered empty.	Danyel Johnson (b) (4)	29 Jan 2021 16:11:24
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User closed query 'Per DM CLR - RQ: Site's response noted. However, Surgery or procedures performed prior to Screening are to be recorded in the Medical History eCRF. Review and ensure to record this data in the MH eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Apr 2021 05:28:09
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:36:26
Query 'Per DM CLR - RQ: Site's response noted. However, Surgery or procedures performed prior to Screening are to be recorded in the Medical History eCRF. Review and ensure to record this data in the MH eCRF as appropriate. ' answered with 'Added to medical history as per query' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	20 Apr 2021 19:45:02
User closed query 'Per CDM: Site response noted; however, PET Scan has not been updated in the Concomitant Procedures page. Please review and reconcile. Else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 08:23:48
User opened query 'Per DM CLR - RQ: Site's response noted. However, Surgery or procedures performed prior to Screening are to be recorded in the Medical History eCRF. Review and ensure to record this data in the MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 13:04:24
User closed query 'Per CDM Re-Query: Site response noted; however, AORTIC VALVE PLACEMENT 2012 AND OVARIAN CYST REMOVAL have not been updated into the MH page. Please review and reconcile. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 13:04:24
Query 'Per CDM Re-Query: Site response noted; however, AORTIC VALVE PLACEMENT 2012 AND OVARIAN CYST REMOVAL have not been updated into the MH page. Please review and reconcile. Thank you.' answered with 'Concomitant procedures completed prior to study enrollment are not be entered' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	01 Apr 2021 18:59:15

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Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per CDM: Site response noted; however, PET Scan has not been updated in the Concomitant Procedures page. Please review and reconcile. Else clarify. Thank you.' answered with 'Added' (Site from DM).	Danyel Johnson (b) (4)	01 Apr 2021 18:55:59
User opened query 'Per CDM Re-Query: Site response noted; however, AORTIC VALVE PLACEMENT 2012 AND OVARIAN CYST REMOVAL have not been updated into the MH page. Please review and reconcile. Thank you.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 13:18:17
User closed query 'Per DM CLR: Per SAE Narrative "61 Y/O FEMALE RANDOMIZED TO ACTIVE IP ON 1/13/2021 LAST DOSE OF IP 2/10/2021 WITH A HISTORY OF AORTIC VALVE PLACEMENT 2012 AND OVARIAN CYST REMOVAL" and "SUBJECT HAD A PET SCAN DONE 2/3/2021". However, these information are not recorded in MH eCRF. Please review if this should be added as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 13:18:17
User opened query 'Per CDM: Site response noted; however, PET Scan has not been updated in the Concomitant Procedures page. Please review and reconcile. Else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 13:13:02
User closed query 'Per DM CLR: Narrative indicates that the subject had PET Scan. However, there is no recorded Concomitant Procedure that match the information. Please update to record the corresponding procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 13:13:02
User closed query 'PV Query: Please send the pathology report , ultrasound report, endometrial biopsy report, CA 123 result and PET scan report, all with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 13:30:06

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative indicates that the subject had PET Scan. However, there is no recorded Concomitant Procedure that match the information. Please update to record the corresponding procedure as appropriate. Otherwise, clarify.' answered with 'Updated' (Site from DM).	Danyel Johnson (b) (4)	24 Mar 2021 12:03:41
Query 'Per DM CLR: Per SAE Narrative "61 Y/O FEMALE RANDOMIZED TO ACTIVE IP ON 1/13/2021 LAST DOSE OF IP 2/10/2021 WITH A HISTORY OF AORTIC VALVE PLACEMENT 2012 AND OVARIAN CYST REMOVAL" and "SUBJECT HAD A PET SCAN DONE 2/3/2021". However, these information are not recorded in MH eCRF. Please review if this should be added as appropriate. Otherwise, provide clarification.' answered with 'Updated' (Site from DM).	Danyel Johnson (b) (4)	24 Mar 2021 12:03:36
Query 'PV Query: Please send the pathology report , ultrasound report, endometrial biopsy report, CA 123 result and PET scan report, all with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Sent today 3/24/2021' (Site from Safety).	Danyel Johnson (b) (4)	24 Mar 2021 12:03:30
User opened query 'Per DM CLR: Per SAE Narrative "61 Y/O FEMALE RANDOMIZED TO ACTIVE IP ON 1/13/2021 LAST DOSE OF IP 2/10/2021 WITH A HISTORY OF AORTIC VALVE PLACEMENT 2012 AND OVARIAN CYST REMOVAL" and "SUBJECT HAD A PET SCAN DONE 2/3/2021". However, these information are not recorded in MH eCRF. Please review if this should be added as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 06:00:09
User opened query 'Per DM CLR: Narrative indicates that the subject had PET Scan. However, there is no recorded Concomitant Procedure that match the information. Please update to record the corresponding procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 18:49:02

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send the pathology report , ultrasound report, endometrial biopsy report, CA 123 result and PET scan report, all with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 14:13:54
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 20:13:50
User closed query 'PV Query: Please send the pathology report , ultrasound report, endometrial biopsy report, CA 123 result and PET scan report, all with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 20:13:48
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Only treatment noted was hysterotomy ' (Site from Safety).	Danyel Johnson (b) (4) (b) (4)	02 Mar 2021 13:28:22
Query 'PV Query: Please send the pathology report , ultrasound report, endometrial biopsy report, CA 123 result and PET scan report, all with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'The above requested information was not included in the initial records received a second request as been sent ' (Site from Safety).	Danyel Johnson (b) (4) (b) (4)	02 Mar 2021 13:27:51

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3832150

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:59

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 17:02:10
User opened query 'PV Query: Please send the pathology report , ultrasound report, endometrial biopsy report, CA 123 result and PET scan report, all with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 17:01:59
User entered '61 y/o female randomized to active IP on 1/13/2021 last dose of IP 2/10/2021 with a history of aortic valve placement 2012 and ovarian cyst removal. Subject reported having a D and C after experiencing post-menopausal bleeding in Oct of 2020. Endometrial biopsy done in Dec 2020 after ultrasound showed thickening of the endometrial stripe. Pathology showed atypical papillary endometrial proliferation suspicious for endometrioid adenocarcinoma. Subject agreed to a TAH/BSO. Pathology from TAH/BSO completed 1/18/2021 noted endometrial cancer. Subject had a PET scan done 2/3/2021 to complete evaluation of noted malignant high grade and sites dx. Including washings, deep invasions, along with sites free of DX. PET scan noted no evidence of hypermetabolic residual or metastatic disease. Subject to have a CA125 every 3 weeks and is being monitored closely.' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	16 Feb 2021 15:05:50
User closed query 'PV Query: Please consider if underlying reason for the hysterectomy met AE/SAE reporting. If not please provide explanation, if so please report.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 17:38:30

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3832150

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:59

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the reason the subject underwent a hysterectomy?' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 17:38:25
User closed query 'PV Query: Please confirm the date of the hysterectomy.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 17:38:11
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 17:38:08
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results obtain to diagnose, and or monitor the event. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 17:38:05
Query 'PV Query: Please consider if underlying reason for the hysterectomy met AE/SAE reporting. If not please provide explanation, if so please report.' answered with 'pending medical records' (Site from Safety).	Danyel Johnson (b) (4)	09 Feb 2021 20:10:59
Query 'PV Query: Please provide the reason the subject underwent a hysterectomy?' answered with 'pending medical records' (Site from Safety).	Danyel Johnson (b) (4)	09 Feb 2021 20:10:47
Query 'PV Query: Please confirm the date of the hysterectomy.' answered with 'Date is stated' (Site from Safety).	Danyel Johnson (b) (4)	09 Feb 2021 20:10:37
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Pending medical records' (Site from Safety).	Danyel Johnson (b) (4)	09 Feb 2021 20:10:20

US3832150

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:59

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results obtain to diagnose, and or monitor the event. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Pending medical records' (Site from Safety).	Danyel Johnson (b) (4)	09 Feb 2021 20:10:07
User opened query 'PV Query: Please consider if underlying reason for the hysterectomy met AE/SAE reporting. If not please provide explanation, if so please report.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 14:52:46
User opened query 'PV Query: Please provide the reason the subject underwent a hysterectomy?' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 14:52:34
User opened query 'PV Query: Please confirm the date of the hysterectomy.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 14:52:25
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 14:52:17
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results obtain to diagnose, and or monitor the event. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 14:52:02
User entered 'Subject contacted the office this morning 1/29/2021 stating that post hysterectomy on 1/18/2021 that the subject was told she has uterine cancer and will need a PET scan to determine treatment options. Requested subject to return to the office to sign a medical records release.'	Danyel Johnson (b) (4)	29 Jan 2021 16:11:24

US3832150

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jan 2021 16:11:24

US3832150

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Jan 2021 16:11:24

US3832150

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:59

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User closed query 'Please add to AE log in Source.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	22 Apr 2021 01:25:17
Query 'Please add to AE log in Source.' answered with 'Added on "Adverse Event" log line #3' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	21 Apr 2021 20:22:57
User opened query 'Please add to AE log in Source.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 19:28:14
User coded data point as SOC: Reproductive system and breast disorders, HLG: Menopause related conditions, HLT: Menopausal effects on the genitourinary tract, PT: Postmenopausal haemorrhage, LLT: Postmenopausal bleeding - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Feb 2021 15:09:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Feb 2021 15:09:58
Data point term sent to Coder	System	16 Feb 2021 15:08:57
User entered 'Post Menopausal Bleeding'	Danyel Johnson (b) (4) (b) (4)	16 Feb 2021 15:08:33

US3832150

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	16 Feb 2021 15:08:33
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered 'No (N)'	Danyel Johnson (b) (4)	16 Feb 2021 15:08:33
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered 'No (N)'	Danyel Johnson (b) (4)	16 Feb 2021 15:08:33
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
Query 'Data entered is non-conformant. Please correct.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:09:15
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Feb 2021 15:54:45
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Feb 2021 15:54:45
User entered 'un Oct 2020' (non-conformant).	Danyel Johnson (b) (4) (b) (4)	19 Feb 2021 15:54:45
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Feb 2021 15:08:33
User entered ' Oct 2020' (non-conformant).	Danyel Johnson (b) (4) (b) (4)	16 Feb 2021 15:08:33

US3832150

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:59

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	16 Feb 2021 15:08:33
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Feb 2021 15:08:33

US3832150

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered 'No (N)'	Danyel Johnson (b) (4)	16 Feb 2021 15:08:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered '18 Jan 2021'	Danyel Johnson (b) (4)	16 Feb 2021 15:08:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:59

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	16 Feb 2021 15:08:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Feb 2021 15:08:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:59

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Danyel Johnson (b) (4)	16 Feb 2021 15:08:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered 'No (N)'	Danyel Johnson (b) (4)	16 Feb 2021 15:08:33
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:59

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered '0'	Danyel Johnson (b) (4)	16 Feb 2021 15:08:33
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:59

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered '0'	Danyel Johnson (b) (4)	16 Feb 2021 15:08:33
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered '0'	Danyel Johnson (b) (4)	16 Feb 2021 15:08:33
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:59

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	16 Feb 2021 15:08:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:59

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	16 Feb 2021 15:08:33
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	16 Feb 2021 15:08:33
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	16 Feb 2021 15:08:33
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered '0'	Danyel Johnson (b) (4)	16 Feb 2021 15:08:33
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered '0'	Danyel Johnson (b) (4)	16 Feb 2021 15:08:33
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered '0'	Danyel Johnson (b) (4)	16 Feb 2021 15:08:33
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User entered 'Not Related (NOT RELATED)'	(b) (4) Danyel Johnson (b) (4)	16 Feb 2021 15:08:33

US3832150

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User entered 'Not Related (NOT RELATED)'	(b) (4) Danyel Johnson (b) (4)	16 Feb 2021 15:08:33

US3832150

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered 'None (NONE)'	Danyel Johnson (b) (4)	16 Feb 2021 15:08:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:59

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered '0'	Danyel Johnson (b) (4)	16 Feb 2021 15:08:33
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered '0'	Danyel Johnson (b) (4)	16 Feb 2021 15:08:33
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered '1'	Danyel Johnson (b) (4)	16 Feb 2021 15:08:33
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:59

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Danyel Johnson (b) (4)	16 Feb 2021 15:08:33

US3832150

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:59

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	16 Feb 2021 15:08:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:59

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	16 Feb 2021 15:08:33
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Feb 2021 15:08:33

US3832150

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Feb 2021 15:08:33

US3832150

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:59

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral infection, LLT: Viral syndrome - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	17 Feb 2021 18:43:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:43:02
Data point term sent to Coder	System	17 Feb 2021 18:30:56
User entered 'Viral Illness'	Danyel Johnson (b) (4) (b) (4)	17 Feb 2021 18:29:57

US3832150

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	17 Feb 2021 18:29:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered 'No (N)'	Danyel Johnson (b) (4)	17 Feb 2021 18:29:57
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered 'No (N)'	Danyel Johnson (b) (4)	17 Feb 2021 18:29:57
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:59

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered '11 Nov 2020'	Danyel Johnson (b) (4)	17 Feb 2021 18:29:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:59

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	17 Feb 2021 18:29:57
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 18:29:57

US3832150

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered 'No (N)'	Danyel Johnson (b) (4)	17 Feb 2021 18:29:57
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered '13 Nov 2020'	Danyel Johnson (b) (4)	17 Feb 2021 18:29:57
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:59

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	17 Feb 2021 18:29:57
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 18:29:57

US3832150

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:59

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	17 Feb 2021 18:30:08
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Danyel Johnson (b) (4)	17 Feb 2021 18:29:57
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered 'No (N)'	Danyel Johnson (b) (4)	17 Feb 2021 18:29:57
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:59

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered '0'	Danyel Johnson (b) (4)	17 Feb 2021 18:29:57
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:59

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered '0'	Danyel Johnson (b) (4)	17 Feb 2021 18:29:57
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered '0'	Danyel Johnson (b) (4)	17 Feb 2021 18:29:57
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:59

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	17 Feb 2021 18:29:57
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:59

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	17 Feb 2021 18:29:57
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	17 Feb 2021 18:29:57
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	17 Feb 2021 18:29:57
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered '0'	Danyel Johnson (b) (4)	17 Feb 2021 18:29:57
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered '0'	Danyel Johnson (b) (4)	17 Feb 2021 18:29:57
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered '0'	Danyel Johnson (b) (4)	17 Feb 2021 18:29:57
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User entered 'Not Related (NOT RELATED)'	(b) (4) Danyel Johnson (b) (4)	17 Feb 2021 18:29:57
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Danyel Johnson (b) (4)	17 Feb 2021 18:29:57
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered 'None (NONE)'	Danyel Johnson (b) (4)	17 Feb 2021 18:29:57
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:59

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Danyel Johnson (b) (4)	17 Feb 2021 18:30:50
	(b) (4)	
User entered '0'	Danyel Johnson (b) (4)	17 Feb 2021 18:29:57
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Danyel Johnson (b) (4)	17 Feb 2021 18:30:50
	(b) (4)	
User entered '1'	Danyel Johnson (b) (4)	17 Feb 2021 18:29:57
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered '0'	Danyel Johnson (b) (4)	17 Feb 2021 18:29:57
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:59

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Danyel Johnson (b) (4)	17 Feb 2021 18:29:57

US3832150

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:59

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	17 Feb 2021 18:29:57
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:59

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	17 Feb 2021 18:29:57
	(b) (4)	

US3832150

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Feb 2021 18:29:57

US3832150

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Feb 2021 18:29:57

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:04:59

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:51
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User closed query 'please enter AE log and concomitant procedure log in the EDC' (Site from CRA).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:28:14
Query 'please enter AE log and concomitant procedure log in the EDC' answered with 'Updated' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	26 Jan 2021 15:36:40
User opened query 'please enter AE log and concomitant procedure log in the EDC' (Site from CRA).	(b) (4), (b) (6)	03 Jan 2021 16:58:51
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	10 Aug 2020 20:39:32

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:04:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: ANTIPROPULSIVES, ATC: ANTIPROPULSIVES, PRODUCT: ELUXADOLINE, PRODUCTSYNONYM: VIBERZI - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	07 Oct 2020 20:27:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Oct 2020 20:27:11
Data point term sent to Coder Coding entries removed.	System Emma Partin (b) (4)	07 Oct 2020 20:06:55 07 Oct 2020 20:06:28
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: ANTIPROPULSIVES, ATC: ANTIPROPULSIVES, PRODUCT: ELUXADOLINE, PRODUCTSYNONYM: VIBERZI - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Aug 2020 22:28:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Aug 2020 22:28:40
Data point term sent to Coder User entered 'Viberzi'	System Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:40:23 10 Aug 2020 20:40:18

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:04:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:40:18
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:04:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
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) (4), (b) (6)	20 Nov 2020 18:08:02
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 'DATA VERIFIED AND UPDATED' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	13 Nov 2020 16:13:37
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)	13 Nov 2020 09:49:00
User closed query 'Per DM CLR: Please review Indication and please note that there is no corresponding MH record that match this condition. Please update to record the corresponding condition as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 13:10:18
Query 'Per DM CLR: Please review Indication and please note that there is no corresponding MH record that match this condition. Please update to record the corresponding condition as appropriate. Otherwise, clarify.' answered with 'corrected' (Site from DM).	Emma Partin (b) (4) (b) (4)	07 Oct 2020 20:06:35
User entered 'colitis' reason for change: Data Entry Error	Emma Partin (b) (4) (b) (4)	07 Oct 2020 20:06:28
User opened query 'Per DM CLR: Please review Indication and please note that there is no corresponding MH record that match this condition. Please update to record the corresponding condition as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 03:23:05
User entered 'Collitus'	Alyssa-Kay Peay (b) (4) (b) (4)	10 Aug 2020 20:40:18

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:04:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered '100'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:40:18
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:04:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:40:18
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:04:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered empty.	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:40:18
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:04:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:40:18
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:04:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered empty.	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:40:18
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:04:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:40:18
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:04:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered empty.	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:40:18
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 11:22:18
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 20:43:57
User entered 'un UNK 2018'	Alyssa-Kay Peay (b) (4) (b) (4)	10 Aug 2020 20:40:18

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered '0'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:40:18
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:40:18
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:04:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered empty.	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:40:18
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:04:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:40:18
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:04:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 20:40:18

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:04:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 20:40:18

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:04:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 20:40:18

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	11 Aug 2020 22:29:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:29:02
Data point term sent to Coder	System	10 Aug 2020 20:41:24
User entered 'Sertraline'	Alyssa-Kay Peay (b) (4) (b) (4)	10 Aug 2020 20:40:46

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:40:46
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'Anxiety'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:40:46
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered '50'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:40:46
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:40:46
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered empty.	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:40:46
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:40:46
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered empty.	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:40:46
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:40:46
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered empty.	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:40:46
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 11:22:25
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 20:43:57
User entered 'un UNK 2009'	Alyssa-Kay Peay (b) (4) (b) (4)	10 Aug 2020 20:40:46

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered '0'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:40:46
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:40:46
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered empty.	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:40:46
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:40:46
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 20:40:46

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 20:40:46

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 20:40:46

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CLONAZEPAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	11 Aug 2020 22:28:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:28:39
Data point term sent to Coder	System	10 Aug 2020 20:41:26
User entered 'Clonazepam'	Alyssa-Kay Peay (b) (4) (b) (4)	10 Aug 2020 20:41:19

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:41:19
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User closed query 'Per DM CLR: Please review Indication and please note that there is no corresponding MH record that match this condition. Please update to record the corresponding condition as appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Please review Indication and please note that there is no corresponding MH record that match this condition. Please update to record the corresponding condition as appropriate. Otherwise, clarify.' answered with 'added to medical history' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 11:10:09
User opened query 'Per DM CLR: Please review Indication and please note that there is no corresponding MH record that match this condition. Please update to record the corresponding condition as appropriate. Otherwise, clarify.' (Site from DM).	Emma Partin (b) (4) (b) (4)	07 Oct 2020 20:15:03
User entered 'Insomnia'	(b) (4), (b) (6)	05 Oct 2020 03:22:47
	Alyssa-Kay Peay (b) (4) (b) (4)	10 Aug 2020 20:41:19

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered '.5'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:41:19
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:41:19
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered empty.	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:41:19
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:41:19
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered empty.	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:41:19
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:41:19
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered empty.	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:41:19
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 11:22:35
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 20:43:57
User entered 'un UNK 2009'	Alyssa-Kay Peay (b) (4) (b) (4)	10 Aug 2020 20:41:19

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered '0'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:41:19
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:41:19
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered empty.	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:41:19
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:41:19
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 20:41:19

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 20:41:19

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 20:41:19

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
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)	11 Aug 2020 22:29:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:29:02
Data point term sent to Coder	System	10 Aug 2020 20:42:27
User entered 'Aspirin'	Alyssa-Kay Peay (b) (4) (b) (4)	10 Aug 2020 20:41:49

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:41:49
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'Cardiac Prophylaxis'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:41:49
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered '81'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:41:49
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:41:49
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:59

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered empty.	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:41:49
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:41:49
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered empty.	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:41:49
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:41:49
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered empty.	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:41:49
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 11:22:43
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 20:43:57
User entered 'un UNK 2012'	Alyssa-Kay Peay (b) (4) (b) (4)	10 Aug 2020 20:41:49

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered '0'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:41:49
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:41:49
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered empty.	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:41:49
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:41:49
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 20:41:49

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 20:41:49

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 20:41:49

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL SULFATE, PRODUCTSYNONYM: VENTOLIN HFA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Aug 2020 10:42:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 10:42:19
Data point term sent to Coder	System	10 Aug 2020 20:43:29
User entered 'Ventolin HFA'	Alyssa-Kay Peay (b) (4) (b) (4)	10 Aug 2020 20:42:58

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:42:58
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'Bronchiectasis'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:42:58
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered '90'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:42:58
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'ug (ug)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:42:58
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered empty.	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:42:58
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'as needed (PRN)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:42:58
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered empty.	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:42:58
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:42:58
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered empty.	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:42:58
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 11:22:54
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 20:43:57
User entered 'un UNK 2018'	Alyssa-Kay Peay (b) (4) (b) (4)	10 Aug 2020 20:42:58

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered '0'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:42:58
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:42:58
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered empty.	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:42:58
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:42:58
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Aug 2020 20:42:58

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Aug 2020 20:42:58

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Aug 2020 20:42:58

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FORMOTEROL FUMARATE;MOMETASONE FUROATE, PRODUCTSYNONYM: DULERA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	11 Aug 2020 22:30:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:30:31
Data point term sent to Coder	System	10 Aug 2020 20:43:30
User entered 'Dulera'	Alyssa-Kay Peay (b) (4) (b) (4)	10 Aug 2020 20:43:26

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:43:26
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'Bronchiectasis'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:43:26
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered '100/5'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:43:26
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'ug (ug)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:43:26
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered empty.	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:43:26
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'as needed (PRN)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:43:26
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered empty.	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:43:26
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:43:26
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered empty.	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:43:26
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 11:23:30
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 20:43:57
User entered 'un UNK 2018'	Alyssa-Kay Peay (b) (4) (b) (4)	10 Aug 2020 20:43:26

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered '0'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:43:26
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:43:26
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered empty.	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:43:26
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 20:43:26
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Aug 2020 20:43:26

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Aug 2020 20:43:26

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Aug 2020 20:43:26

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Feb 2021 18:50:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 18:50:02
Data point term sent to Coder	System	17 Feb 2021 18:40:05
User entered 'Benadryl'	Danyel Johnson (b) (4) (b) (4)	17 Feb 2021 18:39:19

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'No (N)'	Danyel Johnson (b) (4)	17 Feb 2021 18:39:19
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'seasonal ALLERGIC RHINITIS'	(b) (4) Danyel Johnson (b) (4) (b) (4)	17 Feb 2021 18:39:19

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered '25'	Danyel Johnson (b) (4)	17 Feb 2021 18:39:19
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'mg (mg)'	Danyel Johnson (b) (4)	17 Feb 2021 18:39:19
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	17 Feb 2021 18:39:19
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'as needed (PRN)'	Danyel Johnson (b) (4)	17 Feb 2021 18:39:19
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	17 Feb 2021 18:39:19
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'Oral (ORAL)'	Danyel Johnson (b) (4)	17 Feb 2021 18:39:19
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	17 Feb 2021 18:39:19
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:59

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'UN UNK 2018'	Danyel Johnson (b) (4)	17 Feb 2021 18:39:19
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered '0'	Danyel Johnson (b) (4)	17 Feb 2021 18:39:19
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	17 Feb 2021 18:39:19
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	17 Feb 2021 18:39:19
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Feb 2021 18:39:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Feb 2021 18:39:23
User entered 'No (N)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	17 Feb 2021 18:39:23
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Feb 2021 18:39:19
User entered empty.	Danyel Johnson (b) (4)	17 Feb 2021 18:39:19
	(b) (4)	

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 18:39:19

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 18:39:19

US3832150

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 18:39:19

US3832150

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:04:59

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:51
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Danyel Johnson (b) (4)	29 Jan 2021 16:11:56
User entered 'No (N)'	(b) (4)	
	Danyel Johnson (b) (4)	26 Jan 2021 14:43:18
	(b) (4)	

US3832150

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:04:59

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User closed query 'Per DM RQ: Please review the Date of this procedure/Surgery, as it is out of the expected timeframe with the AE of ENDOMETRIAL CANCER (UN OCT 2021 - 18 JAN 2020). Please review and reconcile date of procedure or clarify as necessary. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:10:24
User closed query 'Please add all Con Procedures in EDC to Con Procedure Log in Source so data can be verified. Thank You.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 18:53:35
Query 'Please add all Con Procedures in EDC to Con Procedure Log in Source so data can be verified. Thank You.' answered with 'Source updated' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	21 Apr 2021 18:12:47
User opened query 'Please add all Con Procedures in EDC to Con Procedure Log in Source so data can be verified. Thank You.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 13:38:23
Query 'Per DM RQ: Please review the Date of this procedure/Surgery, as it is out of the expected timeframe with the AE of ENDOMETRIAL CANCER (UN OCT 2021 - 18 JAN 2020). Please review and reconcile date of procedure or clarify as necessary. ' answered with 'Onset data of endometrial cancer is based on endometrial biopsy results ' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	20 Apr 2021 19:46:06
User opened query 'Per DM RQ: Please review the Date of this procedure/Surgery, as it is out of the expected timeframe with the AE of ENDOMETRIAL CANCER (UN OCT 2021 - 18 JAN 2020). Please review and reconcile date of procedure or clarify as necessary. ' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 12:17:00
User closed query 'Per DM CLR: Please review the Date of this procedure/Surgery, as it is out of the expected timeframe with the AE of ENDOMETRIAL CANCER (UN OCT 2021 - 18 JAN 2020). Please review and reconcile date of procedure or clarify as necessary.' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 12:16:48

US3832150

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:04:59

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review the Date of this procedure/Surgery, as it is out of the expected timeframe with the AE of ENDOMETRIAL CANCER (UN OCT 2021 - 18 JAN 2020). Please review and reconcile date of procedure or clarify as necessary.' answered with 'Date is correct ' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	01 Apr 2021 18:57:38
User opened query 'Per DM CLR: Please review the Date of this procedure/Surgery, as it is out of the expected timeframe with the AE of ENDOMETRIAL CANCER (UN OCT 2021 - 18 JAN 2020). Please review and reconcile date of procedure or clarify as necessary.' (Site from DM).	(b) (4), (b) (6) (b) (4)	18 Mar 2021 22:19:28
User entered '18 Jan 2021'	Danyel Johnson (b) (4) (b) (4)	29 Jan 2021 16:12:40

US3832150

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:04:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered 'total abdominal hysterectomy and bilateral salpingo oophorectomy' reason for change:	Danyel Johnson (b) (4)	16 Feb 2021 15:09:38
Data Entry Error	(b) (4)	
User entered 'Total Hysterectomy'	Danyel Johnson (b) (4)	29 Jan 2021 16:12:40
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:04:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User closed query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:09:46
Query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification.' answered with 'Reviewed and updated' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	20 Apr 2021 19:46:23
User opened query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 22:20:11
User closed query 'Per DM CLR: Please review the indication = DIAGNOSTIC as the recorded procedure is therapeutic in nature and not being done for diagnostic purposes. Please confirm if procedure is done for a MedHistory or AE condition and update as appropriate, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 12:49:23
Query 'Per DM CLR: Please review the indication = DIAGNOSTIC as the recorded procedure is therapeutic in nature and not being done for diagnostic purposes. Please confirm if procedure is done for a MedHistory or AE condition and update as appropriate, otherwise provide clarification.' answered with 'Corrected' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	02 Mar 2021 13:29:16
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	02 Mar 2021 13:29:04

US3832150

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:04:59

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review the indication = DIAGNOSTIC as the recorded procedure is therapeutic in nature and not being done for diagnostic purposes. Please confirm if procedure is done for a MedHistory or AE condition and update as appropriate, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 10:27:54
User entered 'Diagnostic (DIAGNOSTIC)'	Danyel Johnson (b) (4) (b) (4)	29 Jan 2021 16:12:40

US3832150

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:04:59

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	29 Jan 2021 16:12:40
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:04:59

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:57
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
Query 'Data entered is non-conformant. Please correct.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:01
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Feb 2021 15:19:07
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Feb 2021 15:19:07
User entered 'un Oct 2020' (non-conformant).	Danyel Johnson (b) (4) (b) (4)	16 Feb 2021 15:19:07
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Feb 2021 15:18:59
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Feb 2021 15:18:59
User entered ' Oct 2020' (non-conformant).	Danyel Johnson (b) (4) (b) (4)	16 Feb 2021 15:18:59
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Feb 2021 15:18:49
User entered 'UN Oct 2020' (non-conformant).	Danyel Johnson (b) (4) (b) (4)	16 Feb 2021 15:18:49

US3832150

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:04:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:57
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User entered 'dilation and curettage'	Danyel Johnson (b) (4)	16 Feb 2021 15:18:49

US3832150

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:04:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:57
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User entered 'Adverse Event (AE)'	Danyel Johnson (b) (4)	16 Feb 2021 15:18:49

US3832150

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:04:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:57
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User entered empty.	Danyel Johnson (b) (4)	16 Feb 2021 15:18:49

US3832150

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:04:59

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:01
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
Query 'Data entered is non-conformant. Please correct.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:06
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Feb 2021 15:22:01
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Feb 2021 15:22:01
User entered 'UN Dec 2020' (non-conformant).	Danyel Johnson (b) (4) (b) (4)	16 Feb 2021 15:22:01
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Feb 2021 15:20:18
User entered ' Dec 2020' (non-conformant).	Danyel Johnson (b) (4) (b) (4)	16 Feb 2021 15:20:18

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:04:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:01
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User entered 'Vaginal ultrasound'	Danyel Johnson (b) (4)	16 Feb 2021 15:20:18

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:04:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:01
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User entered 'Adverse Event (AE)'	Danyel Johnson (b) (4)	16 Feb 2021 15:20:18

US3832150

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:04:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:01
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User entered empty.	Danyel Johnson (b) (4)	16 Feb 2021 15:20:18

US3832150

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:04:59

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:05
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
Query 'Data entered is non-conformant. Please correct.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:11
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Feb 2021 15:22:09
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Feb 2021 15:22:09
User entered 'UN Dec 2020' (non-conformant).	Danyel Johnson (b) (4) (b) (4)	16 Feb 2021 15:22:09
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Feb 2021 15:21:17
User entered ' Dec 2020' (non-conformant).	Danyel Johnson (b) (4) (b) (4)	16 Feb 2021 15:21:17

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:04:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:05
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User entered 'Endometrial biopsy'	Danyel Johnson (b) (4)	16 Feb 2021 15:21:17

US3832150

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:04:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:05
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User entered 'Diagnostic (DIAGNOSTIC)'	Danyel Johnson (b) (4)	16 Feb 2021 15:21:17

US3832150

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:04:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:05
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User entered empty.	Danyel Johnson (b) (4)	16 Feb 2021 15:21:17

US3832150

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:04:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:10
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User entered '03 Feb 2021'	Danyel Johnson (b) (4)	01 Apr 2021 18:54:12

US3832150

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:04:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:10
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User entered 'PET CT of skull and mid thigh'	Danyel Johnson (b) (4)	01 Apr 2021 18:54:12

US3832150

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:04:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:10
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User entered 'Adverse Event (AE)'	Danyel Johnson (b) (4)	01 Apr 2021 18:54:12

US3832150

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:04:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:10
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
User entered empty.	Danyel Johnson (b) (4)	01 Apr 2021 18:54:12

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'USA-US100-2021-MRNA-1273-P301000008'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Yes (Y)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Yes (Y)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Gowdhami'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Mohan'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered '1655 E. Greenville St'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Anderson'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'SC'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered '29621'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:48:37
User entered 'US'	System	01 Feb 2021 15:58:54

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	21 Apr 2021 14:26:40
User entered '7'	System	21 Apr 2021 14:06:22
User entered '6'	System	25 Mar 2021 13:31:10
User entered '5'	System	04 Mar 2021 16:34:37
User entered '4'	System	02 Mar 2021 20:14:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered '3'	System	17 Feb 2021 13:44:03
User entered '2'	System	10 Feb 2021 17:42:03
User entered '1'	System	01 Feb 2021 15:58:54

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'USA-US100-2021-MRNA-1273-P301000008'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Yes (Y)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Yes (Y)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Gowdhami'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Mohan'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered '1655 E. Greenville St'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Anderson'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'SC'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered '29621'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:48:37
User entered 'US'	System	01 Feb 2021 15:58:54

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	21 Apr 2021 14:26:40
User entered '7'	System	21 Apr 2021 14:06:22
User entered '6'	System	25 Mar 2021 13:31:10
User entered '5'	System	04 Mar 2021 16:34:37
User entered '4'	System	02 Mar 2021 20:14:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered '3'	System	17 Feb 2021 13:44:03
User entered '2'	System	10 Feb 2021 17:42:03
User entered '1'	System	01 Feb 2021 15:58:54

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:04:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '01/Feb/2021 15:58'	(b) (4) System	01 Feb 2021 15:58:54

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:04:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:48:37
User entered 'I'	(b) (4), (b) (6)	01 Feb 2021 15:58:54

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'USA-US100-2021-MRNA-1273-P301000008'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Yes (Y)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Yes (Y)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Gowdhami'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Mohan'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered '1655 E. Greenville St'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Anderson'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'SC'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered '29621'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:48:37
User entered 'US'	System	01 Feb 2021 15:58:54

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	21 Apr 2021 14:26:40
User entered '7'	System	21 Apr 2021 14:06:22
User entered '6'	System	25 Mar 2021 13:31:10
User entered '5'	System	04 Mar 2021 16:34:37
User entered '4'	System	02 Mar 2021 20:14:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered '3'	System	17 Feb 2021 13:44:03
User entered '2'	System	10 Feb 2021 17:42:03
User entered '1'	System	01 Feb 2021 15:58:54

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:04:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '10/Feb/2021 12:42'	(b) (4) System	10 Feb 2021 17:42:03

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:04:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:48:37
User entered 'I'	(b) (4), (b) (6)	10 Feb 2021 17:42:03

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'USA-US100-2021-MRNA-1273-P301000008'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Yes (Y)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Yes (Y)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Gowdhami'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Mohan'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered '1655 E. Greenville St'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Anderson'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'SC'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered '29621'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:48:37
User entered 'US'	System	01 Feb 2021 15:58:54

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	21 Apr 2021 14:26:40
User entered '7'	System	21 Apr 2021 14:06:22
User entered '6'	System	25 Mar 2021 13:31:10
User entered '5'	System	04 Mar 2021 16:34:37
User entered '4'	System	02 Mar 2021 20:14:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered '3'	System	17 Feb 2021 13:44:03
User entered '2'	System	10 Feb 2021 17:42:03
User entered '1'	System	01 Feb 2021 15:58:54

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:04:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered '17/Feb/2021 08:44'	(b) (4) System	17 Feb 2021 13:44:03

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:04:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 20:14:15
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
User entered 'I'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 13:44:03

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'USA-US100-2021-MRNA-1273-P301000008'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Yes (Y)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Yes (Y)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Gowdhami'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Mohan'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered '1655 E. Greenville St'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Anderson'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'SC'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered '29621'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:48:37
User entered 'US'	System	01 Feb 2021 15:58:54

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	21 Apr 2021 14:26:40
User entered '7'	System	21 Apr 2021 14:06:22
User entered '6'	System	25 Mar 2021 13:31:10
User entered '5'	System	04 Mar 2021 16:34:37
User entered '4'	System	02 Mar 2021 20:14:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered '3'	System	17 Feb 2021 13:44:03
User entered '2'	System	10 Feb 2021 17:42:03
User entered '1'	System	01 Feb 2021 15:58:54

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:04:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:09:29
User entered '02/Mar/2021 15:14'	(b) (4) System	02 Mar 2021 20:14:26

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:04:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:09:29
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 16:34:24
User entered 'I'	(b) (4), (b) (6)	02 Mar 2021 20:14:26

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'USA-US100-2021-MRNA-1273-P301000008'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Yes (Y)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Yes (Y)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Gowdhami'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Mohan'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered '1655 E. Greenville St'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Anderson'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'SC'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered '29621'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:48:37
User entered 'US'	System	01 Feb 2021 15:58:54

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	21 Apr 2021 14:26:40
User entered '7'	System	21 Apr 2021 14:06:22
User entered '6'	System	25 Mar 2021 13:31:10
User entered '5'	System	04 Mar 2021 16:34:37
User entered '4'	System	02 Mar 2021 20:14:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered '3'	System	17 Feb 2021 13:44:03
User entered '2'	System	10 Feb 2021 17:42:03
User entered '1'	System	01 Feb 2021 15:58:54

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 10:04:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:09:29
User entered '04/Mar/2021 11:34'	(b) (4) System	04 Mar 2021 16:34:37

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 10:04:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:31:13
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:09:29
User entered 'I'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:34:37

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'USA-US100-2021-MRNA-1273-P301000008'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Yes (Y)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Yes (Y)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Gowdhami'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Mohan'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered '1655 E. Greenville St'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Anderson'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'SC'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered '29621'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:48:37
User entered 'US'	System	01 Feb 2021 15:58:54

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	21 Apr 2021 14:26:40
User entered '7'	System	21 Apr 2021 14:06:22
User entered '6'	System	25 Mar 2021 13:31:10
User entered '5'	System	04 Mar 2021 16:34:37
User entered '4'	System	02 Mar 2021 20:14:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered '3'	System	17 Feb 2021 13:44:03
User entered '2'	System	10 Feb 2021 17:42:03
User entered '1'	System	01 Feb 2021 15:58:54

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 10:04:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
User entered '25/Mar/2021 09:31'	(b) (4) System	25 Mar 2021 13:31:10

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 10:04:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:10:56
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:31:13
User entered 'I'	(b) (4), (b) (6)	25 Mar 2021 13:31:10

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'USA-US100-2021-MRNA-1273-P301000008'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Yes (Y)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Yes (Y)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Gowdhami'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Mohan'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered '1655 E. Greenville St'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Anderson'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'SC'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered '29621'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:48:37
User entered 'US'	System	01 Feb 2021 15:58:54

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	21 Apr 2021 14:26:40
User entered '7'	System	21 Apr 2021 14:06:22
User entered '6'	System	25 Mar 2021 13:31:10
User entered '5'	System	04 Mar 2021 16:34:37
User entered '4'	System	02 Mar 2021 20:14:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered '3'	System	17 Feb 2021 13:44:03
User entered '2'	System	10 Feb 2021 17:42:03
User entered '1'	System	01 Feb 2021 15:58:54

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 10:04:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 22:30:08
User entered '21/Apr/2021 10:06'	System	21 Apr 2021 14:06:22

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 10:04:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 22:30:08
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 14:26:20
User entered 'I'	(b) (4), (b) (6)	21 Apr 2021 14:06:22

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

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[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'USA-US100-2021-MRNA-1273-P301000008'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

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Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Yes (Y)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'No (N)'	System	01 Feb 2021 15:57:05

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Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Yes (Y)'	System	01 Feb 2021 15:57:05

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Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Gowdhami'	System	01 Feb 2021 15:57:05

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Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Mohan'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

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[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered '1655 E. Greenville St'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'Anderson'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered 'SC'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:58:48
User entered '29621'	System	01 Feb 2021 15:57:05

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:20:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:48:37
User entered 'US'	System	01 Feb 2021 15:58:54

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	21 Apr 2021 14:26:40
User entered '7'	System	21 Apr 2021 14:06:22
User entered '6'	System	25 Mar 2021 13:31:10
User entered '5'	System	04 Mar 2021 16:34:37
User entered '4'	System	02 Mar 2021 20:14:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:13:49
	(b) (4)	
User entered '3'	System	17 Feb 2021 13:44:03
User entered '2'	System	10 Feb 2021 17:42:03
User entered '1'	System	01 Feb 2021 15:58:54

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 10:04:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 22:30:08
User entered '21/Apr/2021 09:26'	System	21 Apr 2021 14:26:40

US3832150

Folder: SAE USA-US100-2021-MRNA-1273-P301000008

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 10:04:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 22:30:08
User entered 'I'	(b) (4), (b) (6)	21 Apr 2021 14:26:40