

US3892032 (Prod: Synexus Clinical Research US, Inc. - Salt Lake City)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:18:29

All time stamps listed in this document are displayed in GMT

US3892032

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 18:10:22

Generated On: 10 Jun 2021 10:18:29

Participant ID

US3892032

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

US3892032

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:11:54

Generated On: 10 Jun 2021 10:18:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 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

US3892032

Folder: Screening

Form: Demographics

Data signed: (b) (4) 23 Feb 2021 18:11:54

Generated On: 10 Jun 2021 10:18:29

Date of Birth (MMM yyyy)	(b) (6) 1956
Age	64
Age Units	YEARS
Age (Derived)	64
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

US3892032

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 23 Feb 2021 18:11:54

Generated On: 10 Jun 2021 10:18:29

Date of Informed Consent (<i>dd MMM yyyy</i>)	31 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" 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

US3892032

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 23 Feb 2021 18:11:54

Generated On: 10 Jun 2021 10:18:29

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3892032

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 23 Feb 2021 18:11:54

Generated On: 10 Jun 2021 10:18:29

Were any significant conditions reported?

Yes ☒

No ☐

US3892032

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 29 Mar 2021 17:51:24

Generated On: 10 Jun 2021 10:18:29

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2011
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 2011
Start Year (derived)	2011
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3892032

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 29 Mar 2021 17:51:24

Generated On: 10 Jun 2021 10:18:29

Condition	RESTLESS LEG SYNDROME
Start date (dd MMM yyyy)	UN UNK 2011
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 2011
Start Year (derived)	2011
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3892032

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 29 Mar 2021 17:51:24

Generated On: 10 Jun 2021 10:18:29

Condition	SENSORY PERIPHERAL NEUROPATHY BILATERAL LEGS
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

US3892032

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 29 Mar 2021 17:51:24

Generated On: 10 Jun 2021 10:18:29

Condition	LOWER BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3892032

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 29 Mar 2021 17:51:24

Generated On: 10 Jun 2021 10:18:29

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3892032

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 29 Mar 2021 17:51:24

Generated On: 10 Jun 2021 10:18:29

Condition	DYSMENORRHEA
Start date (dd MMM yyyy)	UN UNK 1990
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 2000
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	JAN 2000
Stop Year (derived)	2000

US3892032

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 29 Mar 2021 17:51:24

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 29 Mar 2021 17:51:24

Generated On: 10 Jun 2021 10:18:29

Condition	OBESITY
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3892032

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 29 Mar 2021 17:51:24

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 29 Mar 2021 17:51:24

Generated On: 10 Jun 2021 10:18:29

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3892032

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 29 Mar 2021 17:51:24

Generated On: 10 Jun 2021 10:18:29

Condition	BILATERAL DRY EYES
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)	_____

US3892032

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 29 Mar 2021 17:51:24

Generated On: 10 Jun 2021 10:18:29

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	JAN 2000
Stop Year (derived)	2000

US3892032

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 29 Mar 2021 17:51:24

Generated On: 10 Jun 2021 10:18:29

Condition	PERIPHERAL EDEMA (BILATERAL- LOWER EXTREMITY)
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

US3892032

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 29 Mar 2021 17:51:24

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 29 Mar 2021 17:51:24

Generated On: 10 Jun 2021 10:18:29

Condition	ESOPHAGEAL STRICTURE
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)	_____

US3892032

Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 29 Mar 2021 17:51:24

Generated On: 10 Jun 2021 10:18:29

Condition	USE OF RADIESSE FACIAL FILLER FOR COSMETIC USE
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

US3892032

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 18:11:54

Generated On: 10 Jun 2021 10:18:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	31 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	10:44 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 10:44
Height (<i>xxx.x</i>)	161 cm
Weight (<i>xxx.x</i>)	109.4 kg
BMI (<i>xxx.x</i>)	42.20516 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3892032

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:11:54

Generated On: 10 Jun 2021 10:18:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 AUG 2020

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

US3892032

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 23 Feb 2021 18:11:54

Generated On: 10 Jun 2021 10:18:29

Date of assessment (dd MMM yyyy) 31 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) UN UNK 2000

Date of surgery unknown False

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

Date of last menstruation unknown False

US3892032

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 18:11:54

Generated On: 10 Jun 2021 10:18:29

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 RETIRED

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3892032

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 18:11:54

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:11:55

Generated On: 10 Jun 2021 10:18:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 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

US3892032

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 23 Feb 2021 18:11:55

Generated On: 10 Jun 2021 10:18:29

What was the date of randomization? (dd MMM yyyy) 31 AUG 2020

What was the participant's randomization number? 145452

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

US3892032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 18:11:55

Generated On: 10 Jun 2021 10:18:29

Height	ND - Not Done
Weight	ND - Not Done

US3892032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 18:11:55

Generated On: 10 Jun 2021 10:18:29

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)	31 AUG 2020
Time of assessment (00:00-23:59)	10:44 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 10:44
Temperature (xxx.x)	97.1 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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3892032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 18:11:55

Generated On: 10 Jun 2021 10:18:29

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	31 AUG 2020
Time of assessment (00:00-23:59)	12:35 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 12:35
Temperature (xxx.x)	97.1 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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3892032

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:11:55

Generated On: 10 Jun 2021 10:18:29

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.

US3892032

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 18:11:55

Generated On: 10 Jun 2021 10:18:29

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) 31 AUG 2020

What was the treatment time? (00:00-23:59) 12:02 (24 HR)

Treatment Date and Time (derived) 31 AUG 2020 12:02

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

US3892032

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:11:55

Generated On: 10 Jun 2021 10:18:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	31 AUG 2020
Collection time (00:00-23:59)	11:50 (24 HR)
Collection date and time (derived)	31 AUG 2020 11:50

US3892032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 18:11:55

Generated On: 10 Jun 2021 10:18:29

Collection date (dd MMM yyyy)			31 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:30	31 AUG 2020 11:30
Nasopharyngeal Swab 2	No		

US3892032

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:11:55

Generated On: 10 Jun 2021 10:18:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐
No ☒

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

PC Time Stamp 31 AUG 2020 12:36

PC Open Date & Time 31 AUG 2020 12:22

PC Close Date & Time 31 AUG 2020 14:52

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

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

97.8 °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	31 AUG 2020 19:49
PC Open Date & Time	31 AUG 2020 15:47
PC Close Date & Time	01 SEP 2020 11:59

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:18:29

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

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

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:18:29

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 20:10

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:18:29

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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 21:19

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

04 SEP 2020 20:19

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:18:29

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

98.6 °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

06 SEP 2020 02:34

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:18:29

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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 20:10

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

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

31 AUG 2020 12:37

PC Open Date & Time

31 AUG 2020 12:22

PC Close Date & Time

31 AUG 2020 14:52

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

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

31 AUG 2020 19:50

PC Open Date & Time

31 AUG 2020 15:47

PC Close Date & Time

01 SEP 2020 11:59

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:18:29

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 ☐

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.**

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

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:18:29

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

02 SEP 2020 20:10

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:18:29

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

03 SEP 2020 21:20

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:18:29

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

04 SEP 2020 20:20

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 02:34

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:18:29

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

06 SEP 2020 20:10

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 12:37
PC Open Date & Time	31 AUG 2020 12:22
PC Close Date & Time	31 AUG 2020 14:52

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 19:51
PC Open Date & Time	31 AUG 2020 15:47
PC Close Date & Time	01 SEP 2020 11:59

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

58 of 4365

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:29

Yes ☐

PC Time stamp

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:29

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

60 of 4365

EAB) (1725)

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:29

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 20:11
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003

62 of 4365

EAB) (1725)

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:29

		Yes <input type="checkbox"/>
PC Time stamp	03 SEP 2020 21:21	
PC Open Date & Time	03 SEP 2020 12:00	
PC Close Date & Time	04 SEP 2020 11:59	

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

64 of 4365

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:29

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 20:21
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:29

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

66 of 4365

EAB) (1725)

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:29

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 02:35
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:29

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

68 of 4365

EAB) (1725)

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:29

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 20:12
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3892032

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 09:10

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3892032

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

08 SEP 2020 09:10

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3892032

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

08 SEP 2020 19:24

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3892032

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 8

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

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 08 SEP 2020 09:10

PC Open Date & Time 07 SEP 2020 12:00

PC Close Date & Time 08 SEP 2020 11:59

US3892032

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 08 SEP 2020 09:11

PC Open Date & Time 07 SEP 2020 12:00

PC Close Date & Time 08 SEP 2020 11:59

US3892032

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of **CHILLS** you
are experiencing

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

PC Open Date & Time 07 SEP 2020 12:00

PC Close Date & Time 08 SEP 2020 11:59

PC Time stamp 08 SEP 2020 09:11

US3892032

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	08 SEP 2020 09:11
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3892032

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:11:54

Generated On: 10 Jun 2021 10:18:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3892032

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:11:54

Generated On: 10 Jun 2021 10:18:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892032

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:10:28

Generated On: 10 Jun 2021 10:18:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3892032

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:10:28

Generated On: 10 Jun 2021 10:18:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892032

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:10:28

Generated On: 10 Jun 2021 10:18:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3892032

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:10:28

Generated On: 10 Jun 2021 10:18:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892032

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:11:55

Generated On: 10 Jun 2021 10:18:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 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

US3892032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 18:11:55

Generated On: 10 Jun 2021 10:18:29

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)	28 SEP 2020
Time of assessment (00:00-23:59)	10:38 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 10:38
Temperature (xxx.x)	98.3 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)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3892032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 18:11:55

Generated On: 10 Jun 2021 10:18:29

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)	28 SEP 2020
Time of assessment (00:00-23:59)	12:27 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 12:27
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3892032

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:11:55

Generated On: 10 Jun 2021 10:18:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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

US3892032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 18:11:55

Generated On: 10 Jun 2021 10:18:29

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) 28 SEP 2020

What was the treatment time? (00:00-23:59) 11:52 (24 HR)

Treatment Date and Time (derived) 28 SEP 2020 11:52

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

US3892032

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:11:55

Generated On: 10 Jun 2021 10:18:29

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 SEP 2020

Collection time (00:00-23:59)

11:07 (24 HR)

Collection date and time (derived)

28 SEP 2020 11:07

US3892032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 18:11:55

Generated On: 10 Jun 2021 10:18:29

Collection date (dd MMM yyyy)			28 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:13	28 SEP 2020 11:13
Nasopharyngeal Swab 2	No		

US3892032

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:11:55

Generated On: 10 Jun 2021 10:18:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

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

97.4 °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

28 SEP 2020 12:30

PC Open Date & Time

28 SEP 2020 12:12

PC Close Date & Time

28 SEP 2020 14:42

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.6 °F

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

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

PC Time Stamp	28 SEP 2020 21:26
PC Open Date & Time	28 SEP 2020 15:37
PC Close Date & Time	29 SEP 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	29 SEP 2020 20:04
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	01 OCT 2020 04:04
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:18:29

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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

02 OCT 2020 00:16

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

03 OCT 2020 00:40

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:18:29

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

98.1 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

03 OCT 2020 22:22

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	04 OCT 2020 20:29
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 8

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

05 OCT 2020 23:55

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 9

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	95.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	06 OCT 2020 23:31
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 10

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.4 °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

08 OCT 2020 00:21

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

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

28 SEP 2020 12:31

PC Open Date & Time

28 SEP 2020 12:12

PC Close Date & Time

28 SEP 2020 14:42

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

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

28 SEP 2020 21:27

PC Open Date & Time

28 SEP 2020 15:37

PC Close Date & Time

29 SEP 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:18:29

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

29 SEP 2020 20:05

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:18:29

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

01 OCT 2020 04:05

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:18:29

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

02 OCT 2020 00:17

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:18:29

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

03 OCT 2020 00:41

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:18:29

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

03 OCT 2020 22:23

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:18:29

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

04 OCT 2020 20:30

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

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

No ☒

Yes ☐

PC Time stamp	28 SEP 2020 12:32
PC Open Date & Time	28 SEP 2020 12:12
PC Close Date & Time	28 SEP 2020 14:42

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

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

No ☒

Yes ☐

PC Time stamp	28 SEP 2020 21:27
PC Open Date & Time	28 SEP 2020 15:37
PC Close Date & Time	29 SEP 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:29

		Yes <input type="checkbox"/>
PC Time stamp	29 SEP 2020 20:07	
PC Open Date & Time	29 SEP 2020 12:00	
PC Close Date & Time	30 SEP 2020 11:59	

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☒

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

116 of 4365

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:29

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 04:06
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

118 of 4365

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:29

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 00:18
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:29

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 ☒

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:29

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 00:42
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☒

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

122 of 4365

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:29

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 22:24
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:29

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)

124 of 4365

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:29

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 20:31
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 05 OCT 2020 23:55

PC Open Date & Time 05 OCT 2020 12:00

PC Close Date & Time 06 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 06 OCT 2020 23:31

PC Open Date & Time 06 OCT 2020 12:00

PC Close Date & Time 07 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 OCT 2020 00:22

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Headache_Day(11)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 OCT 2020 10:25

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Headache_Day(12)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 OCT 2020 20:47

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Headache_Day(13)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your

None ☒

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 10 OCT 2020 23:39

PC Open Date & Time 10 OCT 2020 12:00

PC Close Date & Time 11 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp 05 OCT 2020 23:55

PC Open Date & Time 05 OCT 2020 12:00

PC Close Date & Time 06 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☒

PC Time Stamp

06 OCT 2020 23:31

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

08 OCT 2020 00:22

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☒

PC Time Stamp

09 OCT 2020 10:25

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

09 OCT 2020 20:48

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

10 OCT 2020 23:39

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 8

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☒

PC Time stamp 05 OCT 2020 23:55

PC Open Date & Time 05 OCT 2020 12:00

PC Close Date & Time 06 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 9

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 06 OCT 2020 23:32

PC Open Date & Time 06 OCT 2020 12:00

PC Close Date & Time 07 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 10

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 08 OCT 2020 00:22

PC Open Date & Time 07 OCT 2020 12:00

PC Close Date & Time 08 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 11

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 09 OCT 2020 10:25

PC Open Date & Time 08 OCT 2020 12:00

PC Close Date & Time 09 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 12

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 09 OCT 2020 20:48

PC Open Date & Time 09 OCT 2020 12:00

PC Close Date & Time 10 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 13

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

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 10 OCT 2020 23:39

PC Open Date & Time 10 OCT 2020 12:00

PC Close Date & Time 11 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 05 OCT 2020 23:56

PC Open Date & Time 05 OCT 2020 12:00

PC Close Date & Time 06 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 06 OCT 2020 23:32

PC Open Date & Time 06 OCT 2020 12:00

PC Close Date & Time 07 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 08 OCT 2020 00:23

PC Open Date & Time 07 OCT 2020 12:00

PC Close Date & Time 08 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 09 OCT 2020 10:26

PC Open Date & Time 08 OCT 2020 12:00

PC Close Date & Time 09 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 09 OCT 2020 20:48

PC Open Date & Time 09 OCT 2020 12:00

PC Close Date & Time 10 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 10 OCT 2020 23:40

PC Open Date & Time 10 OCT 2020 12:00

PC Close Date & Time 11 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 8

Select one response below to indicate the level of your

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 ☐

PC Time stamp 05 OCT 2020 23:56

PC Open Date & Time 05 OCT 2020 12:00

PC Close Date & Time 06 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(9)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 9

Select one response below to indicate the level of your

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 ☐

PC Time stamp

06 OCT 2020 23:33

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(10)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 10

Select one response below to indicate the level of your

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 ☐

PC Time stamp

08 OCT 2020 00:22

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(11)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 11

Select one response below to indicate the level of your

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 ☐

PC Time stamp 09 OCT 2020 10:26

PC Open Date & Time 08 OCT 2020 12:00

PC Close Date & Time 09 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(12)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 12

Select one response below to indicate the level of your

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 ☐

PC Time stamp

09 OCT 2020 20:48

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(13)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 13

Select one response below to indicate the level of your

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 ☐

PC Time stamp 10 OCT 2020 23:40

PC Open Date & Time 10 OCT 2020 12:00

PC Close Date & Time 11 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(14)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 14

Select one response below to indicate the level of your

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 ☐

PC Time stamp

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(15)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 15

Select one response below to indicate the level of your

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 ☐

PC Time stamp

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☒

Prevents daily activity and
requires medical attention ☐

PC Open Date & Time 05 OCT 2020 12:00

PC Close Date & Time 06 OCT 2020 11:59

PC Time stamp 05 OCT 2020 23:56

US3892032

Folder: Diary Dose 2 (1)

Form: Chills_Day(9)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☐

No interference with activity ☐

Some interference with activity not requiring medical attention ☒

Prevents daily activity and requires medical attention ☐

PC Open Date & Time	06 OCT 2020 12:00
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PC Close Date & Time	07 OCT 2020 11:59
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PC Time stamp	06 OCT 2020 23:33
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US3892032

Folder: Diary Dose 2 (1)

Form: Chills_Day(10)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

PC Open Date & Time 07 OCT 2020 12:00

PC Close Date & Time 08 OCT 2020 11:59

PC Time stamp 08 OCT 2020 00:23

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	05 OCT 2020 23:56
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	06 OCT 2020 23:34
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/> Yes <input checked="" type="checkbox"/>
PC Time stamp	08 OCT 2020 00:23
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	09 OCT 2020 10:26
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	09 OCT 2020 20:48
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT	DAY 13
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	10 OCT 2020 23:40
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT	DAY 15
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="radio"/>
	Yes <input type="radio"/>
PC Time stamp	
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3892032

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:11:54

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:10:28

Generated On: 10 Jun 2021 10:18:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892032

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:11:54

Generated On: 10 Jun 2021 10:18:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3892032

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:11:54

Generated On: 10 Jun 2021 10:18:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892032

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:11:54

Generated On: 10 Jun 2021 10:18:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3892032

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:11:54

Generated On: 10 Jun 2021 10:18:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892032

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:11:55

Generated On: 10 Jun 2021 10:18:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 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

US3892032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 18:11:55

Generated On: 10 Jun 2021 10:18:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 OCT 2020
Time of assessment (00:00-23:59)	10:25 (24 HR)
Vital Signs Date and Time (derived)	27 OCT 2020 10:25
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	98 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3892032

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:11:55

Generated On: 10 Jun 2021 10:18:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 OCT 2020

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

US3892032

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:11:55

Generated On: 10 Jun 2021 10:18:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	27 OCT 2020
Collection time (00:00-23:59)	10:56 (24 HR)
Collection date and time (derived)	27 OCT 2020 10:56

US3892032

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:11:55

Generated On: 10 Jun 2021 10:18:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 NOV 2020 12:50:15
Patient Cloud Open Date & Time	31 OCT 2020 00:01
Patient Cloud Close Date & Time	04 NOV 2020 23:59

US3892032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 NOV 2020 13:13:05

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3892032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	True
Cough	True
Shortness of breath	True
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	True
New loss of smell	False
Sore throat	False
Congestion	True
Runny nose	True
Nausea	True
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	16 NOV 2020 19:11:20
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2020 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 DEC 2020 00:42:48
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 DEC 2020 12:00:38

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

16 DEC 2020 00:02:35

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 DEC 2020 13:38:22

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 DEC 2020 00:06:54
Patient Cloud Open Date & Time	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 JAN 2021 00:01:28
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	13 JAN 2021 00:04:50
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

20 JAN 2021 08:31:44

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

30 JAN 2021 17:59:29

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

06 FEB 2021 18:02:08

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 FEB 2021 05:47:08
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

17 FEB 2021 00:03:35

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

24 FEB 2021 07:01:57

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

03 MAR 2021 00:02:41

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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	10 MAR 2021 00:02:48
Patient Cloud Open Date & Time	10 MAR 2021 00:01
Patient Cloud Close Date & Time	14 MAR 2021 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

17 MAR 2021 03:54:23

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

24 MAR 2021 01:20:37

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

31 MAR 2021 00:48:04

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

08 APR 2021 08:06:09

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

16 APR 2021 16:26:18

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

21 APR 2021 09:34:03

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 <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°F/38°C)	False
Chills	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
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 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"/>

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

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



Date and time of submission	28 APR 2021 02:09:35
Patient Cloud Open Date & Time	28 APR 2021 00:01
Patient Cloud Close Date & Time	02 MAY 2021 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 <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"/>

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 <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"/>

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 <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"/>

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 306

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

☐

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

No ☐

Yes ☐

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

Fever (Temperature \geq 100.4°F/38°C)

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

☐

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

No ☐

Yes ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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="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"/>

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 <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"/>

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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
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Patient Cloud Close Date & Time	15 AUG 2021 23:59
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US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 <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"/>

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 <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"/>

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01
Patient Cloud Close Date & Time	03 OCT 2021 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 404

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

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

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

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

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

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

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

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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"/>

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
Patient Cloud Close Date & Time	31 OCT 2021 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 439

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

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

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

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

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

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

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

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 <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"/>

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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="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"/>

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	02 JAN 2022 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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"/>

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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"/>

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 <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"/>

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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"/>

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 <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"/>

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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="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"/>

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01
Patient Cloud Close Date & Time	12 JUN 2022 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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"/>

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 <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"/>

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

DAY 712

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

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

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

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

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

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

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

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01
Patient Cloud Close Date & Time	14 AUG 2022 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 <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"/>

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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="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"/>

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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"/>

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 <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"/>

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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
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Patient Cloud Close Date & Time	16 OCT 2022 23:59
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US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01
Patient Cloud Close Date & Time	30 OCT 2022 23:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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="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"/>

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

[Patient Cloud Close Date & Time](#)

06 NOV 2022 23:59

US3892032

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 10:18:29

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
Yes	No	01 MAR 2021 16:02:13

US3892032

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:11:54

Generated On: 10 Jun 2021 10:18:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3892032

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:11:54

Generated On: 10 Jun 2021 10:18:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892032

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:10:28

Generated On: 10 Jun 2021 10:18:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3892032

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:10:28

Generated On: 10 Jun 2021 10:18:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892032

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:10:28

Generated On: 10 Jun 2021 10:18:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3892032

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:10:28

Generated On: 10 Jun 2021 10:18:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892032

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:10:28

Generated On: 10 Jun 2021 10:18:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3892032

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:10:28

Generated On: 10 Jun 2021 10:18:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892032

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	06 APR 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3892032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

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) _____

US3892032

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 APR 2021

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

US3892032

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

06 APR 2021

Collection time (00:00-23:59)

10:30 (24 HR)

Collection date and time (derived)

06 APR 2021 10:30

US3892032

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892032

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:29

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

Date of Contact 01 OCT 2020

Time of Contact

Date and Time of Contact (derived)

Type of Contact

Clinic Visit - Scheduled ☐

Clinical Visit - Unscheduled ☐

Safety Call ☒

Convalescent Tele-visit ☐

Has the subject reported symptoms of SARS-COV-2?

Yes ☒

No ☐

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

Symptom Day

Day 1	<input checked="" type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	28 SEP 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

388 of 4365

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

389 of 4365

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

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"/>

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	29 SEP 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

392 of 4365

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

393 of 4365

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

	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	01 OCT 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

396 of 4365

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

	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	02 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	98.6 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 type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

400 of 4365

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 type="radio"/>
	Mild	<input checked="" 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"/>

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

	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	03 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.4 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

404 of 4365

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" 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 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

	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	04 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.4 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)

408 of 4365

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

	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	05 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	95 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.4 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

412 of 4365

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

	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	06 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.2 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 type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

416 of 4365

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

417 of 4365

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

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 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

	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	07 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	96.3 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 type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

420 of 4365

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input 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"/>

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

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 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input checked="" type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

	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	08 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.6 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		424 of 4365
EAB) (1725)		

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input checked="" 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"/>

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

	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	09 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	95 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.5 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

428 of 4365

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input checked="" 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"/>

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	10 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.5 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

432 of 4365

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

	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 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

433 of 4365

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input checked="" 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"/>

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 OCT 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	97.9 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		436 of 4365
EAB) (1725)		

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

	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 checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

437 of 4365

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

Date of Visit 01 OCT 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒ No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☐ No ☒

Date of Test 03 OCT 2020

Type of Test Performed Nasopharyngeal Swab ☐ Nasal Swab ☐ Saliva Test ☒ Other ☐

Other, specify

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐ No ☒

If yes, provide lab information below

Lab/ Institution Test Performed

CLIA Certified? Yes ☐ No ☐

COVID-19 Positive (CSA Programming Field Only) 0

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

Date of Contact	12 JAN 2021
Time of Contact	11:15
Date and Time of Contact (derived)	12 JAN 2021 11:15
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

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"/>

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	11 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" 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 type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

443 of 4365

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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 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 checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

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"/>

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	12 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	95 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.3 F
-------------	--------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" 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 type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

447 of 4365

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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 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 checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

	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	13 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	92 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.9 F
-------------	--------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input checked="" type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

451 of 4365

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input 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 checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

	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	14 JAN 2021	
Assessment Not Done	False	
O2 Saturation	92 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input checked="" type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input checked="" type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	455 of 4365	

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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"/>

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

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 checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

	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	15 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	93 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.1 F
-------------	--------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input checked="" 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 type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

459 of 4365

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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"/>

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

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 checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input checked="" 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

Date of Visit	13 JAN 2021
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	13 JAN 2021
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

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

Date of Contact 16 NOV 2020

Time of Contact

Date and Time of Contact (derived)

Type of Contact

Clinic Visit - Scheduled ☐

Clinical Visit - Unscheduled ☒

Safety Call ☐

Convalescent Tele-visit ☐

Has the subject reported symptoms of SARS-COV-2?

Yes ☒

No ☐

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 18:10:27

Generated On: 10 Jun 2021 10:18:29

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"/>

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 18:10:27

Generated On: 10 Jun 2021 10:18:29

	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	93 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	99.0 F
-------------	--------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" 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 type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" 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)

465 of 4365

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 18:10:27

Generated On: 10 Jun 2021 10:18:29

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of 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)

466 of 4365

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 18:10:27

Generated On: 10 Jun 2021 10:18:29

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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 18:10:27

Generated On: 10 Jun 2021 10:18:29

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"/>

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 18:10:27

Generated On: 10 Jun 2021 10:18:29

	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	96 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.4 F
-------------	--------

Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

469 of 4365

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 18:10:27

Generated On: 10 Jun 2021 10:18:29

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input 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"/>

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 18:10:27

Generated On: 10 Jun 2021 10:18:29

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" 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 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 18:10:27

Generated On: 10 Jun 2021 10:18:29

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 18:10:27

Generated On: 10 Jun 2021 10:18:29

	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	18 NOV 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" 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 type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" 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)	473 of 4365	

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 18:10:27

Generated On: 10 Jun 2021 10:18:29

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

474 of 4365

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 18:10:27

Generated On: 10 Jun 2021 10:18:29

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 checked="" 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 18:10:27

Generated On: 10 Jun 2021 10:18:29

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 18:10:27

Generated On: 10 Jun 2021 10:18:29

	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	19 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	96.8 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input 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 type="checkbox"/>
	Mild	<input checked="" 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		477 of 4365
EAB) (1725)		

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 18:10:27

Generated On: 10 Jun 2021 10:18:29

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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)

478 of 4365

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 18:10:27

Generated On: 10 Jun 2021 10:18:29

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 23 Feb 2021 18:10:26

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 23 Feb 2021 18:10:28

Generated On: 10 Jun 2021 10:18:29

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	03 OCT 2020
Day 5	Yes	05 OCT 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)	

US3892032

Folder: Illness Visit (2)

Form: Saliva Collection

Data signed: (b) (4) 23 Feb 2021 18:10:28

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: Illness Visit (3)

Form: Saliva Collection

Data signed: (b) (4) 23 Feb 2021 18:10:28

Generated On: 10 Jun 2021 10:18:29

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	16 JAN 2021
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3892032

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:10:28

Generated On: 10 Jun 2021 10:18:29

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 SICKD1

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 18:10:28

Generated On: 10 Jun 2021 10:18:29

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) _____

US3892032

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:10:28

Generated On: 10 Jun 2021 10:18:29

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.

US3892032

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 23 Feb 2021 18:10:28

Generated On: 10 Jun 2021 10:18:29

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

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

US3892032

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 18:10:28

Generated On: 10 Jun 2021 10:18:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	16 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	10:44 (24 HR)
Vital Signs Date and Time (derived)	16 NOV 2020 10:44
Temperature (<i>xxx.x</i>)	99.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	86 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3892032

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:10:28

Generated On: 10 Jun 2021 10:18:29

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.

US3892032

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 23 Feb 2021 18:10:28

Generated On: 10 Jun 2021 10:18:29

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

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

US3892032

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:10:28

Generated On: 10 Jun 2021 10:18:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 18:10:28

Generated On: 10 Jun 2021 10:18:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	13 JAN 2021
Time of assessment (<i>00:00-23:59</i>)	08:30 (24 HR)
Vital Signs Date and Time (derived)	13 JAN 2021 08:30
Temperature (<i>xxx.x</i>)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	93 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3892032

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:10:28

Generated On: 10 Jun 2021 10:18:29

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.

US3892032

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 23 Feb 2021 18:10:28

Generated On: 10 Jun 2021 10:18:29

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

13 JAN 2021

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:10:25

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 18:10:25

Generated On: 10 Jun 2021 10:18:29

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) _____

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:10:25

Generated On: 10 Jun 2021 10:18:29

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.

US3892032

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 23 Feb 2021 18:10:25

Generated On: 10 Jun 2021 10:18:29

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☒

Date of Collection

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:10:25

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 18:10:25

Generated On: 10 Jun 2021 10:18:29

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) _____

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:10:25

Generated On: 10 Jun 2021 10:18:29

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.

US3892032

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 23 Feb 2021 18:10:25

Generated On: 10 Jun 2021 10:18:29

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☒

Date of Collection

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:10:25

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 18:10:25

Generated On: 10 Jun 2021 10:18:29

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) _____

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:10:25

Generated On: 10 Jun 2021 10:18:29

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.

US3892032

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 23 Feb 2021 18:10:25

Generated On: 10 Jun 2021 10:18:29

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☒

Date of Collection

US3892032

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:10:28

Generated On: 10 Jun 2021 10:18:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	15 FEB 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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US3892032

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

Form: Unblinding

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

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>)	15 FEB 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3892032

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 18:10:28

Generated On: 10 Jun 2021 10:18:29

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3892032

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 18:10:28

Generated On: 10 Jun 2021 10:18:29

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 FEB 2021
Time of assessment (00:00-23:59)	12:56 (24 HR)
Vital Signs Date and Time (derived)	15 FEB 2021 12:56
Temperature (xxx.x)	97.2 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)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3892032

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 18:10:28

Generated On: 10 Jun 2021 10:18:29

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 FEB 2021
Time of assessment (00:00-23:59)	13:33 (24 HR)
Vital Signs Date and Time (derived)	15 FEB 2021 13:33
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)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	156 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	96 mmHg
Diastolic Blood Pressure units	MMHG

US3892032

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

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:10:28

Generated On: 10 Jun 2021 10:18:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 FEB 2021

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

US3892032

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

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 18:10:28

Generated On: 10 Jun 2021 10:18:29

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) 15 FEB 2021

What was the treatment time? (00:00-23:59) 13:01 (24 HR)

Treatment Date and Time (derived) 15 FEB 2021 13:01

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

US3892032

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:10:28

Generated On: 10 Jun 2021 10:18:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	15 FEB 2021
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Collection time (00:00-23:59)	11:39 (24 HR)
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Collection date and time (derived)	15 FEB 2021 11:39
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US3892032

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 18:10:28

Generated On: 10 Jun 2021 10:18:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 FEB 2021
Collection time (00:00 - 23:59)	11:49
Collection Date and Time (derived)	15 FEB 2021 11:49

US3892032

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

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:10:28

Generated On: 10 Jun 2021 10:18:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892032

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3892032

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3892032

Folder: OL-D29 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	12 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	09:30 (24 HR)
Vital Signs Date and Time (derived)	12 MAR 2021 09:30
Temperature (<i>xxx.x</i>)	99.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	93 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	92 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3892032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

Height	ND - Not Done
Weight	ND - Not Done

US3892032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

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)	12 MAR 2021
Time of assessment (00:00-23:59)	09:30 (24 HR)
Vital Signs Date and Time (derived)	12 MAR 2021 09:30
Temperature (xxx.x)	99.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	93 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3892032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 MAR 2021
Time of assessment (00:00-23:59)	10:37 (24 HR)
Vital Signs Date and Time (derived)	12 MAR 2021 10:37
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3892032

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 MAR 2021

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

US3892032

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

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) 12 MAR 2021

What was the treatment time? (00:00-23:59) 10:05 (24 HR)

Treatment Date and Time (derived) 12 MAR 2021 10:05

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

US3892032

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3892032

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892032

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3892032

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892032

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3892032

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	06 APR 2021
Time of assessment (<i>00:00-23:59</i>)	10:21 (24 HR)
Vital Signs Date and Time (derived)	06 APR 2021 10:21
Temperature (<i>xxx.x</i>)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	90 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3892032

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 APR 2021

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

US3892032

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	06 APR 2021
Collection time (<i>00:00-23:59</i>)	10:30 (24 HR)
Collection date and time (derived)	06 APR 2021 10:30

US3892032

Folder: Unscheduled 06 Oct 2020

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 23 Feb 2021 18:11:55

Generated On: 10 Jun 2021 10:18:29

Visit Date	06 OCT 2020
------------	-------------

Please check all assessments that apply for this visit

Physical Exam	True
---------------	------

Vital Signs	False
-------------	-------

Immunogenicity Assessment	False
---------------------------	-------

Pregnancy Test	False
----------------	-------

US3892032

Folder: Unscheduled 06 Oct 2020

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:11:55

Generated On: 10 Jun 2021 10:18:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 OCT 2020

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

US3892032

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Mar 2021 16:21:35

Generated On: 10 Jun 2021 10:18:29

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3892032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:29

AEID

Adverse event

WORSENING OF SEASONAL
ALLERGIES

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)

7 SEP 2020

Start time (00:00-23:59)

07:00 (24 HR)

AE start date and time (derived)

7 SEP 2020 07:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

8 SEP 2020

End time (00:00-23:59)

18:00 (24 HR)

AE End Date and Time (derived)

8 SEP 2020 18:00

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

538 of 4365

EAB) (1725)

US3892032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:29

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)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3892032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:29

AEID

Adverse event

ALLERGIC CONJUNCTIVITIS

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

27 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

28 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

PRODUCTION RELEASE (v12.003

540 of 4365

EAB) (1725)

US3892032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:29

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 Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3892032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:18:29

AEID	
Adverse event	VIRAL SYNDROME
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)	29 SEP 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)	12 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

PRODUCTION RELEASE (v12.003
EAB) (1725)

542 of 4365

US3892032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:18:29

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 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	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

US3892032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:18:29

AEID

Adverse event

UPPER RESPIRATORY TRACT
INFECTION

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)

14 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

19 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

544 of 4365

EAB) (1725)

US3892032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:18:29

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 type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3892032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:18:29

AEID

Adverse event

WORSENING OF
GASTROESOPHAGEAL REFLUX
DISEASE

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)

15 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)

15 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐
Grade 2/Moderate ☒
Grade 3/Severe ☐
Grade 4 ☐

Is the adverse event serious?

Yes ☐
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐
No ☐
Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

546 of 4365

EAB) (1725)

US3892032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:18:29

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 type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT REPORTED THAT ACID REFLUX STARTED AWAKENING HER AT NIGHT SOMETIME IN OCTOBER. HER HCP INCREASED THE OMEPRAZOLE DOSAGE AND SYMPTOMS RETURNED TO BASELINE.
Serious Adverse Event Derived (CSA Programming Field Only)	0

PRODUCTION RELEASE (v12.003
EAB) (1725)

547 of 4365

US3892032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:18:29

Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3892032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:18:29

AEID

Adverse event

RASH ON MID BACK
(URTICARIA)

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)

12 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

28 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

EAB) (1725)

549 of 4365

US3892032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:18:29

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 type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3892032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:18:29

AEID	
Adverse event	ACUTE SINUSITIS
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 JAN 2021
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)	21 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	
Persistent or significant disability or incapacity	False

PRODUCTION RELEASE (v12.003
EAB) (1725)

551 of 4365

US3892032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:18:29

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 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	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

US3892032

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:18:29

AEID	
Adverse event	ACUTE BRONCHITIS
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)	13 JAN 2021
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)	22 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 type="radio"/> Grade 3/Severe <input checked="" 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	
Persistent or significant disability or incapacity	False

PRODUCTION RELEASE (v12.003
EAB) (1725)

553 of 4365

US3892032

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:18:29

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 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	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

US3892032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:18:29

AEID	
Adverse event	NAUSEA
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 JAN 2021
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 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	
Persistent or significant disability or incapacity	False

PRODUCTION RELEASE (v12.003
EAB) (1725)

555 of 4365

US3892032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:18:29

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 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	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

US3892032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:18:29

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	31 AUG 2020
Start time (00:00-23:59)	19:51 (24 HR)
AE start date and time (derived)	31 AUG 2020 19:51
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	08 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

PRODUCTION RELEASE (v12.003
EAB) (1725)

557 of 4365

US3892032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:18:29

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	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	

US3892032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:18:29

SYMPTOM INITIALLY
CAPTURED AS SOLICITED
ADVERSE EVENT IN DIARY
ONLY BUT REQUIRED AE
PAGE/EVENT DUE TO STILL
ONGOING AFTER DAY 7. IT
ALSO OVERLAPPED AE OF
ALLERGIES TO WILDFIRE
SMOKE, BUT IS CONSIDERED
TO BE SOLICITED AE LIKELY
RELATED TO VACCINE AS IT
PERSISTED LONGER THAN
SYMPTOMS FOR AE # 1.

Serious Adverse Event Derived (CSA Programming Field Only)	0
--	---

Medically Attended AE Derived (CSA Programming Field Only)	0
--	---

Admitted to ICU Derived (CSA Programming Field Only)	
--	--

US3892032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:18:29

AEID	
Adverse event	HEADACHE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	29 SEP 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)	11 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

PRODUCTION RELEASE (v12.003
EAB) (1725)

560 of 4365

US3892032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:18:29

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3892032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:18:29

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	29 SEP 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)	12 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" 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	
Persistent or significant disability or incapacity	False

PRODUCTION RELEASE (v12.003
EAB) (1725)

562 of 4365

US3892032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:18:29

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3892032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:18:29

AEID	
Adverse event	GENERALIZED MYALGIA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	29 SEP 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)	09 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" 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	
Persistent or significant disability or incapacity	False

PRODUCTION RELEASE (v12.003
EAB) (1725)

564 of 4365

US3892032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:18:29

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3892032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:18:29

AEID

Adverse event

GENERALIZED ARTHRALGIA

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

29 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

10 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

PRODUCTION RELEASE (v12.003

566 of 4365

EAB) (1725)

US3892032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:18:29

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3892032

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:18:29

AEID	
Adverse event	CHILLS
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	29 SEP 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)	06 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

PRODUCTION RELEASE (v12.003
EAB) (1725)

568 of 4365

US3892032

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:18:29

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3892032

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:18:29

AEID	
Adverse event	NAUSEA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	29 SEP 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)	11 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

PRODUCTION RELEASE (v12.003
EAB) (1725)

570 of 4365

US3892032

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:18:29

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3892032

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:18:29

AEID	
Adverse event	VOMITING
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	29 SEP 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)	11 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

PRODUCTION RELEASE (v12.003
EAB) (1725)

572 of 4365

US3892032

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:18:29

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3892032

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:18:29

AEID

Adverse event

MENISCUS TEAR LEFT KNEE

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)

22 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒
No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐
Grade 2/Moderate ☒
Grade 3/Severe ☐
Grade 4 ☐

Is the adverse event serious?

Yes ☐
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐
No ☐
Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity False

PRODUCTION RELEASE (v12.003
EAB) (1725)

574 of 4365

US3892032

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:18:29

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 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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input 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)	

US3892032

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:18:29

AEID	USA-US209-2021-MRNA-1273-P30 1000005
Adverse event	STRESS FRACTURE LEFT FOOT
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)	22 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	22 APR 2021
Hospital Discharge Date (dd MMM yyyy)	26 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

576 of 4365

US3892032

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:18:29

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 type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input 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	SUBJECT WAS HOSPITALIZED FOR AN ELECTIVE SURGICAL PROCEDURE TO REPAIR FIX DAMAGE LEFT FOOT. ALTHOUGH THE SURGERY WAS ELECTIVE AND NOT EMERGENCY SURGERY, IT WILL BE CONSIDERED AN SAE PER SECTION 8.3.3
Serious Adverse Event Derived (CSA Programming Field Only)	1

PRODUCTION RELEASE (v12.003
EAB) (1725)

577 of 4365

US3892032

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 10:18:29

AEID	
Adverse event	
Was this a medically-attended AE?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Was this a Solicited Adverse Reaction?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Start date (dd MMM yyyy)	
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="checkbox"/> No <input type="checkbox"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="checkbox"/> Grade 2/Moderate <input type="checkbox"/> Grade 3/Severe <input type="checkbox"/> Grade 4 <input type="checkbox"/>
Is the adverse event serious?	Yes <input type="checkbox"/> No <input type="checkbox"/>
AE is serious due To (check all that apply)	
Death	
Life threatening	
Requires inpatient or prolongation of existing Hospitalization	
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	

US3892032

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 10:18:29

Congenital anomaly or birth defect		
Other medically important event		
Relationship to investigational product	Not Related	<input type="checkbox"/>
	Related	<input type="checkbox"/>
	Not Applicable	<input type="checkbox"/>
Relationship to Study Procedure	Not Related	<input type="checkbox"/>
	Related	<input type="checkbox"/>
	Not Applicable	<input type="checkbox"/>
Action taken with investigational product	None	<input type="checkbox"/>
	Dose Delayed	<input type="checkbox"/>
	Investigational Product	<input type="checkbox"/>
	Withdrawn	<input type="checkbox"/>
	Not Applicable	<input type="checkbox"/>
Other action taken (check all that apply)		
None		
Concomitant Medication		
Concomitant Procedure		
Outcome	Fatal	<input type="checkbox"/>
	Not Recovered/Not Resolved	<input type="checkbox"/>
	Recovered/Resolved	<input type="checkbox"/>
	Recovered/Resolved with Sequelae	<input type="checkbox"/>
	Recovering/Resolving	<input type="checkbox"/>
	Unknown	<input type="checkbox"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:		
Narrative		
Serious Adverse Event Derived (CSA Programming Field Only)		
Medically Attended AE Derived (CSA Programming Field Only)		
Admitted to ICU Derived (CSA Programming Field Only)		

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Apr 2021 16:25:46

Generated On: 10 Jun 2021 10:18:29

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

Yes ☒

No ☐

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

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

Name of Medication TRAZADONE

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

582 of 4365

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

	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 2011	
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"/>

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

Name of Medication PRAMIPEXOLE

Prophylaxis Yes ☐
No ☒

Indication RESTLESS LEG SYNDROM

Dose per administration 1.0

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)

584 of 4365

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

	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 2011	
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"/>

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

Name of Medication PREGABALIN

Prophylaxis Yes ☐
No ☒

Indication SENSORY PERIPHERAL
NEUROPATHY BILATERAL
LEGS

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

586 of 4365

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2015	
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"/>

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

Name of Medication CYCLOBENZAPRINE

Prophylaxis Yes ☐
No ☒

Indication LOWER BACK PAIN

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)

588 of 4365

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

	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 2015	
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"/>

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

Name of Medication ESTRODIAL

Prophylaxis Yes ☐
No ☒

Indication POST MENOPAUSAL
(HORMONE REPLACEMENT)

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

590 of 4365

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2003
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"/>

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

Name of Medication HYDROCODONE-ACETAMINOP
HEN

Prophylaxis Yes ☐
No ☒

Indication LOWER BACK PAIN

Dose per administration 7.5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

592 of 4365

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2015	
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"/>

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

Name of Medication DIAZEPAM

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

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)

594 of 4365

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

	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 2013	
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"/>

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GASTROESOPHAGEAL REFLUX
DISEASE

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

596 of 4365

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	12 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

Name of Medication RESTASIS 0.05%

Prophylaxis Yes ☐
No ☒

Indication BILATERAL DRY EYES

Dose per administration 1

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

If dose unit is Other, specify DROP IN EACH EYE

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)

598 of 4365

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	OPHTHALMIC	
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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

Name of Medication AMOXICILLIN

Prophylaxis Yes ☒
No ☐

Indication DENTAL PROPHYLAXIS

Dose per administration 1000

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

600 of 4365

EAB) (1725)

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

	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)		24 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 SEP 2020
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"/>

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

Name of Medication THERAFLU MULTISYMPOM:
ACETAMINOPHEN,
DYPHENHYDRAMINE HCL,
PHENYLEPHRINE HCL

Prophylaxis Yes ☐
No ☒

Indication VIRAL SYNDROME AND
HEADACHE

Dose per administration 1

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

If dose unit is Other, specify PACKET

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

602 of 4365

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	12 OCT 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="checkbox"/>	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication VIRAL SYNDROME

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

604 of 4365

EAB) (1725)

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

	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)		08 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 OCT 2020
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"/>

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication RASH ON MID BACK
(URTICARIA)

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

606 of 4365

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

Name of Medication THERAFLU MULTISYMPOM:
ACETAMINOPHEN,
DYPHENHYDRAMINE HCL,
PHENYLEPHRINE HCL

Prophylaxis Yes ☐
No ☒

Indication UPPER RESPIRATORY
INFECTION

Dose per administration 1

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

If dose unit is Other, specify PACKET

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

608 of 4365

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	14 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	19 NOV 2020	
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"/>	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF GERD

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

610 of 4365

EAB) (1725)

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

	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)		12 NOV 2020
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)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication URTICARIA

Dose per administration 20

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

612 of 4365

EAB) (1725)

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

	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)	18 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	28 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

Name of Medication ATROVENT

Prophylaxis Yes ☐
No ☒

Indication ACUTE BRONCHITIS

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

614 of 4365

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	14 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		20 JAN 2021
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"/>

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

Name of Medication DOXYCYCLINE

Prophylaxis Yes ☐
No ☒

Indication ACUTE SINUSITIS

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

616 of 4365

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

Name of Medication MUCINEX
DM(DEXTROMETHORPHAN
HBR - GUAIFENESIN)

Prophylaxis Yes ☐
No ☒

Indication ACUTE SINUSITIS

Dose per administration 60-1200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

618 of 4365

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 JAN 2021
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"/>

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication NAUSEA

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

620 of 4365

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

	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)	11 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 JAN 2021
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"/>

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

Name of Medication	THERAFLU MULTISYMP TOM: ACETAMINOPHEN, DYPHENHYDRAMINE HCL, PHENYLEPHRINE HCL
--------------------	--

Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
-------------	--

Indication	MYALGIA AND ARTHRALGIA
------------	------------------------

Dose per administration	1
-------------------------	---

Dose unit	mg <input type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input checked="" type="checkbox"/>
-----------	---

If dose unit is Other, specify	PACKET
--------------------------------	--------

Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input checked="" type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
-----------	---

If frequency is Other, specify	
--------------------------------	--

Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/>
-------------------------	---

PRODUCTION RELEASE (v12.003
EAB) (1725)

622 of 4365

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	10 OCT 2020	
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"/>

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

Name of Medication RADIESSE

Prophylaxis Yes ☐
No ☒

Indication ELECTIVE

Dose per administration 0.8

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

624 of 4365

EAB) (1725)

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 12 Apr 2021 16:25:45

Generated On: 10 Jun 2021 10:18:29

	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 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) UN UNK 2019		
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"/>

US3892032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Feb 2021 18:10:25

Generated On: 10 Jun 2021 10:18:29

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3892032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 26 Apr 2021 22:39:57

Generated On: 10 Jun 2021 10:18:29

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
24 SEP 2020	ROUTINE DENTAL CLEANING	Other	DENTAL PROPHYLAXIS
10 NOV 2020	BARIUM SWALLOW	Diagnostic	
13 JAN 2021	CHEST X-RAY	Adverse Event	
05 APR 2021	MRI LEFT KNEE	Adverse Event	
22 APR 2021	SURGICAL REPAIR LEFT FOOT	Adverse Event	

US3892032

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:18:29

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

US3892032

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:18:29

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 ☐

US3892032

Folder: SAE USA-US209-2021-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 22:39:57

Generated On: 10 Jun 2021 10:18:29

SAEID	USA-US209-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	ADAMS
Site Address: Street	5251 S GREEN ST
Site Address: City	MURRAY
Site Address: State	UT
Site Address: Postal Code	84123
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3892032

Folder: SAE USA-US209-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 22:39:57

Generated On: 10 Jun 2021 10:18:29

SAEID	USA-US209-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	ADAMS
Site Address: Street	5251 S GREEN ST
Site Address: City	MURRAY
Site Address: State	UT
Site Address: Postal Code	84123
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	26/APR/2021 14:25
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

US3892032 (Prod: Synexus Clinical Research US, Inc. - Salt Lake City)

US3892032

Form: Participant Creation

Generated On: 10 Jun 2021 10:18:29

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:55:02
User entered 'US3892032'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 16:15:06

US3892032

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 15:55:43
User entered 'Yes (Y)'	chase Carnahan (b) (4)	31 Aug 2020 18:13:56

US3892032

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:55:43
User entered '31 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 16:15:07

US3892032

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 15:55:43
User entered 'Clinic (Clinic)'	chase Carnahan (b) (4)	31 Aug 2020 18:13:56

US3892032

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered 'SCRN'	System	31 Aug 2020 18:13:56

US3892032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:18:29

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:02:35
User entered (b) (6) 1956'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 16:15:10

US3892032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:18:29

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:02:35
User entered '64'	chase Carnahan (b) (4)	31 Aug 2020 18:14:18

US3892032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:18:29

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered 'YEARS'	System	31 Aug 2020 18:14:18

US3892032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:18:29

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered '64'	System	31 Aug 2020 18:14:33

US3892032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:18:29

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:02:35
User entered 'Female (F)'	chase Carnahan (b) (4)	31 Aug 2020 18:14:18

US3892032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:18:29

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:02:35
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:14:18

US3892032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:18:29

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:02:35
User entered 'l'	chase Carnahan (b) (4)	31 Aug 2020 18:14:18

US3892032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:18:29

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:02:35
User entered '0'	chase Carnahan (b) (4)	31 Aug 2020 18:14:18

US3892032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:18:29

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:02:35
User entered '0'	chase Carnahan (b) (4)	31 Aug 2020 18:14:18

US3892032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:18:29

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:02:35
User entered '0'	chase Carnahan (b) (4)	31 Aug 2020 18:14:18

US3892032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:18:29

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:02:35
User entered '0'	chase Carnahan (b) (4)	31 Aug 2020 18:14:18

US3892032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:18:29

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:02:35
User entered '0'	chase Carnahan (b) (4)	31 Aug 2020 18:14:18

US3892032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:18:29

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:02:35
User entered empty.	chase Carnahan (b) (4)	31 Aug 2020 18:14:18

US3892032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:18:29

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:02:35
User entered '0'	chase Carnahan (b) (4)	31 Aug 2020 18:14:18

US3892032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:18:29

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:02:35
User entered '0'	chase Carnahan (b) (4)	31 Aug 2020 18:14:18

US3892032

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:18:29

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:02:12
User entered '31 Aug 2020'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:14:33

US3892032

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered 'Aug 2020'	System	31 Aug 2020 18:14:33

US3892032

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered '2020'	System	31 Aug 2020 18:14:33

US3892032

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:18:29

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:02:12
User entered 'Amendment 3 (3)'	chase Carnahan (b) (4)	31 Aug 2020 18:14:33

US3892032

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:02:12
User entered 'Yes (Y)'	chase Carnahan (b) (4)	31 Aug 2020 18:14:33

US3892032

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:18:29

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:02:12
User entered empty.	chase Carnahan (b) (4)	31 Aug 2020 18:14:33

US3892032

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:18:29

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:02:12
User entered empty.	chase Carnahan (b) (4)	31 Aug 2020 18:14:33

US3892032

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:18:29

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:02:12
User entered 'No (N)'	chase Carnahan (b) (4)	31 Aug 2020 18:14:33

US3892032

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:18:29

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:02:12
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 16:15:07

US3892032

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:18:29

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered 'I'	System	31 Aug 2020 18:14:33

US3892032

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:06:35
User entered 'Yes (Y)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:14:04

US3892032

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:18:29

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:02:47
User entered 'Yes (Y)'	chase Carnahan (b) (4)	31 Aug 2020 18:14:45

US3892032

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:18:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:07:59
User coded data point as SOC: Psychiatric disorders, HLTG: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:54:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:54:31
Data point term sent to Coder	System	31 Aug 2020 21:53:53
User entered 'Insomnia'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:52:57

US3892032

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:07:59
User entered 'un UNK 2011'	chase Carnahan (b) (4)	31 Aug 2020 21:52:57

US3892032

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:07:59
User entered '0'	chase Carnahan (b) (4)	31 Aug 2020 21:52:57

US3892032

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:18:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:07:59
User entered 'Yes (Y)'	chase Carnahan (b) (4)	31 Aug 2020 21:52:57

US3892032

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:07:59
User entered empty.	chase Carnahan (b) (4)	31 Aug 2020 21:52:57

US3892032

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:18:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:07:59
User entered '0'	chase Carnahan (b) (4)	31 Aug 2020 21:52:57

US3892032

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered 'Jan 2011'	System	31 Aug 2020 21:52:57

US3892032

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered '2011'	System	31 Aug 2020 21:52:57

US3892032

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered empty.	System	31 Aug 2020 21:52:57

US3892032

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered empty.	System	31 Aug 2020 21:52:57

US3892032

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:18:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:07:59
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Restless legs syndrome, LLT: Restless leg syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:54:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:54:32
Data point term sent to Coder	System	31 Aug 2020 21:53:53
User entered 'restless leg syndrome'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:53:28

US3892032

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:07:59
User entered 'un UNK 2011'	chase Carnahan (b) (4)	31 Aug 2020 21:53:28

US3892032

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:07:59
User entered '0'	chase Carnahan (b) (4)	31 Aug 2020 21:53:28

US3892032

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:18:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:07:59
User entered 'Yes (Y)'	chase Carnahan (b) (4)	31 Aug 2020 21:53:28

US3892032

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:07:59
User entered empty.	chase Carnahan (b) (4)	31 Aug 2020 21:53:28

US3892032

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:18:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:07:59
User entered '0'	chase Carnahan (b) (4)	31 Aug 2020 21:53:28

US3892032

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered 'Jan 2011'	System	31 Aug 2020 21:53:28

US3892032

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered '2011'	System	31 Aug 2020 21:53:28

US3892032

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered empty.	System	31 Aug 2020 21:53:28

US3892032

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered empty.	System	31 Aug 2020 21:53:28

US3892032

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:18:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:19:58
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Peripheral sensory neuropathy, LLT: Sensory peripheral neuropathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Sep 2020 18:11:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Sep 2020 18:11:45
Data point term sent to Coder	System	18 Sep 2020 16:52:05
DataPoint Un-verified.	Andryelle Toledo (b) (4)	18 Sep 2020 16:51:57
Coding entries removed.	(b) (4) Andryelle Toledo (b) (4)	18 Sep 2020 16:51:57
User entered 'SENSORY PERIPHERAL NEUROPATHY BILATERAL LEGS' reason for change: Data Entry Error	(b) (4) Andryelle Toledo (b) (4)	18 Sep 2020 16:51:57
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:07:59
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Peripheral neuropathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:54:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:54:32
Data point term sent to Coder	System	31 Aug 2020 21:53:53
User entered 'peripheral neuropathy'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:53:50

US3892032

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:07:59
User entered 'un UNK 2015'	chase Carnahan (b) (4)	31 Aug 2020 21:53:50

US3892032

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:07:59
User entered '0'	chase Carnahan (b) (4)	31 Aug 2020 21:53:50

US3892032

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:18:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:07:59
User entered 'Yes (Y)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:53:50

US3892032

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:07:59
User entered empty.	chase Carnahan (b) (4)	31 Aug 2020 21:53:50

US3892032

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:18:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:07:59
User entered '0'	chase Carnahan (b) (4)	31 Aug 2020 21:53:50

US3892032

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered 'Jan 2015'	System	31 Aug 2020 21:53:50

US3892032

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered '2015'	System	31 Aug 2020 21:53:50

US3892032

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered empty.	System	31 Aug 2020 21:53:50

US3892032

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered empty.	System	31 Aug 2020 21:53:50

US3892032

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:18:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:07:59
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Low back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:55:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:55:47
Data point term sent to Coder	System	31 Aug 2020 21:54:54
User entered 'lower back pain'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:54:05

US3892032

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:07:59
User entered 'un UNK 2015'	chase Carnahan (b) (4)	31 Aug 2020 21:54:05

US3892032

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:07:59
User entered '0'	chase Carnahan (b) (4)	31 Aug 2020 21:54:05

US3892032

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:18:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:07:59
User entered 'Yes (Y)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:54:05

US3892032

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:07:59
User entered empty.	chase Carnahan (b) (4)	31 Aug 2020 21:54:05

US3892032

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:18:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:07:59
User entered '0'	chase Carnahan (b) (4)	31 Aug 2020 21:54:05

US3892032

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered 'Jan 2015'	System	31 Aug 2020 21:54:05

US3892032

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered '2015'	System	31 Aug 2020 21:54:05

US3892032

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered empty.	System	31 Aug 2020 21:54:05

US3892032

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered empty.	System	31 Aug 2020 21:54:05

US3892032

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:18:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:07:59
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:55:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:55:47
Data point term sent to Coder	System	31 Aug 2020 21:54:54
User entered 'anxiety'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:54:18

US3892032

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:07:59
User entered 'un UNK 2013'	chase Carnahan (b) (4)	31 Aug 2020 21:54:18

US3892032

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:07:59
User entered '0'	chase Carnahan (b) (4)	31 Aug 2020 21:54:18

US3892032

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:18:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:07:59
User entered 'Yes (Y)'	chase Carnahan (b) (4)	31 Aug 2020 21:54:18

US3892032

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:07:59
User entered empty.	chase Carnahan (b) (4)	31 Aug 2020 21:54:18

US3892032

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:18:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:07:59
User entered '0'	chase Carnahan (b) (4)	31 Aug 2020 21:54:18

US3892032

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered 'Jan 2013'	System	31 Aug 2020 21:54:18

US3892032

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered '2013'	System	31 Aug 2020 21:54:18

US3892032

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered empty.	System	31 Aug 2020 21:54:18

US3892032

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered empty.	System	31 Aug 2020 21:54:18

US3892032

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:18:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:07:59
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation and uterine bleeding NEC, PT: Dysmenorrhoea, LLT: Dysmenorrhea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:55:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:55:47
Data point term sent to Coder	System	31 Aug 2020 21:54:54
User entered 'dysmenorrhea'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:54:32

US3892032

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:07:59
User entered 'un UNK 1990'	chase Carnahan (b) (4)	31 Aug 2020 21:54:32

US3892032

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:07:59
User entered '0'	chase Carnahan (b) (4)	31 Aug 2020 21:54:32

US3892032

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:18:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:07:59
User entered 'No (N)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	03 Sep 2020 15:51:46
User entered 'Yes (Y)'	chase Carnahan (b) (4)	31 Aug 2020 21:54:32

US3892032

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:28:21
DataPoint Un-verified.	Leslie Iverson (b) (4)	11 Nov 2020 21:11:29
User entered 'UN UNK 2000' reason for change:	(b) (4)	
Data Entry Error	Leslie Iverson (b) (4)	11 Nov 2020 21:11:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:36:50
DataPoint Un-verified.	Andryelle Toledo (b) (4)	20 Oct 2020 19:42:31
	(b) (4)	
User entered 'UN UNK 2003' reason for change:	Andryelle Toledo (b) (4)	20 Oct 2020 19:42:31
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:07:59
User entered 'UN UNK 2000' reason for change:	Andryelle Toledo (b) (4)	03 Sep 2020 15:51:46
Data Entry Error	(b) (4)	
User entered empty.	chase Carnahan (b) (4)	31 Aug 2020 21:54:32
	(b) (4)	

US3892032

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:18:29

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
User closed query 'Should "obesity" be added to MH? Kindly update if the PI feels this is relevant history for this subject. Thank you.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 20:03:57
User closed query 'Kindly add 'seasonal allergies' to MH in EDC per subject source this is noted.' (Site from CRA).	(b) (4), (b) (6)	18 Sep 2020 21:14:45
Query 'Should "obesity" be added to MH? Kindly update if the PI feels this is relevant history for this subject. Thank you.' answered with 'update' (Site from CRA).	Andryelle Toledo (b) (4) (b) (4)	18 Sep 2020 16:52:24
Query 'Kindly add 'seasonal allergies' to MH in EDC per subject source this is noted.' answered with 'update' (Site from CRA).	Andryelle Toledo (b) (4) (b) (4)	18 Sep 2020 16:36:30
User opened query 'Should "obesity" be added to MH? Kindly update if the PI feels this is relevant history for this subject. Thank you.' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 16:21:59
User opened query 'Kindly add 'seasonal allergies' to MH in EDC per subject source this is noted.' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 16:09:17
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:07:59
User entered '0'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:54:32

US3892032

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered 'Jan 1990'	System	31 Aug 2020 21:54:32

US3892032

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered '1990'	System	31 Aug 2020 21:54:32

US3892032

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered 'Jan 2000'	System	11 Nov 2020 21:11:29
User entered 'Jan 2003'	System	20 Oct 2020 19:42:31
User entered 'Jan 2000'	System	03 Sep 2020 15:51:46
User entered empty.	System	31 Aug 2020 21:54:32

US3892032

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered '2000'	System	11 Nov 2020 21:11:29
User entered '2003'	System	20 Oct 2020 19:42:31
User entered '2000'	System	03 Sep 2020 15:51:46
User entered empty.	System	31 Aug 2020 21:54:32

US3892032

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:18:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:19:58
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 21:32:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 21:32:41
Data point term sent to Coder	System	16 Sep 2020 21:31:55
User entered 'Seasonal Allergies'	Andryelle Toledo (b) (4) (b) (4)	16 Sep 2020 21:31:12
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4) (b) (4)	16 Sep 2020 21:30:43
DataPoint inactivated with code reason code Data not required.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:54:50

US3892032

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:19:58
User entered 'un UNK 2000'	Andryelle Toledo (b) (4)	16 Sep 2020 21:31:12
DataPoint activated with code reason code Data required.	(b) (4) Andryelle Toledo (b) (4)	16 Sep 2020 21:30:43
DataPoint inactivated with code reason code Data not chase Carnahan required.	(b) (4) (b) (4)	31 Aug 2020 21:54:50

US3892032

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:19:58
User entered '0'	Andryelle Toledo (b) (4)	16 Sep 2020 21:31:12
DataPoint activated with code reason code Data required.	(b) (4) Andryelle Toledo (b) (4)	16 Sep 2020 21:30:43
DataPoint inactivated with code reason code Data not chase Carnahan required.	(b) (4) (b) (4)	31 Aug 2020 21:54:50

US3892032

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:18:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:19:58
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	16 Sep 2020 21:31:12
DataPoint activated with code reason code Data required.	(b) (4) Andryelle Toledo (b) (4)	16 Sep 2020 21:30:43
DataPoint inactivated with code reason code Data not chase Carnahan required.	(b) (4) (b) (4)	31 Aug 2020 21:54:50

US3892032

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:19:58
User entered empty.	Andryelle Toledo (b) (4)	16 Sep 2020 21:31:12
DataPoint activated with code reason code Data required.	(b) (4) Andryelle Toledo (b) (4)	16 Sep 2020 21:30:43
DataPoint inactivated with code reason code Data not chase Carnahan required.	(b) (4) (b) (4)	31 Aug 2020 21:54:50

US3892032

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:18:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:19:58
User entered '0'	Andryelle Toledo (b) (4)	16 Sep 2020 21:31:12
DataPoint activated with code reason code Data required.	(b) (4) Andryelle Toledo (b) (4)	16 Sep 2020 21:30:43
DataPoint inactivated with code reason code Data not chase Carnahan required.	(b) (4) (b) (4)	31 Aug 2020 21:54:50

US3892032

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered 'Jan 2000'	System	16 Sep 2020 21:31:12
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	16 Sep 2020 21:30:43
DataPoint inactivated with code reason code Data not chase Carnahan required.	(b) (4)	31 Aug 2020 21:54:50

US3892032

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered '2000'	System	16 Sep 2020 21:31:12
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	16 Sep 2020 21:30:43
DataPoint inactivated with code reason code Data not chase Carnahan required.	(b) (4)	31 Aug 2020 21:54:50

US3892032

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered empty.	System	16 Sep 2020 21:31:12
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	16 Sep 2020 21:30:43
DataPoint inactivated with code reason code Data not chase Carnahan required.	(b) (4)	31 Aug 2020 21:54:50

US3892032

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered empty.	System	16 Sep 2020 21:31:12
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	16 Sep 2020 21:30:43
DataPoint inactivated with code reason code Data not chase Carnahan required.	(b) (4)	31 Aug 2020 21:54:50

US3892032

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:18:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:19:58
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 16:53:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 16:53:53
Data point term sent to Coder	System	18 Sep 2020 16:53:06
User entered 'obesity'	Andryelle Toledo (b) (4) (b) (4)	18 Sep 2020 16:52:34

US3892032

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:19:58
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	01 Oct 2020 13:33:16
User entered 'un UNK 1990' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:33:16
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	18 Sep 2020 16:52:34
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	18 Sep 2020 16:52:34

US3892032

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:19:58
User entered '0'	Andryelle Toledo (b) (4)	18 Sep 2020 16:52:34

US3892032

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:18:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:19:58
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	18 Sep 2020 16:52:34

US3892032

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:19:58
User entered empty.	Andryelle Toledo (b) (4)	18 Sep 2020 16:52:34

US3892032

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:18:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:19:58
User entered '0'	Andryelle Toledo (b) (4)	18 Sep 2020 16:52:34

US3892032

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered 'Jan 1990'	System	01 Oct 2020 13:33:16
User entered empty.	System	18 Sep 2020 16:52:34

US3892032

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered '1990'	System	01 Oct 2020 13:33:16
User entered empty.	System	18 Sep 2020 16:52:34

US3892032

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered empty.	System	18 Sep 2020 16:52:34

US3892032

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered empty.	System	18 Sep 2020 16:52:34

US3892032

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:18:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:36:50
User closed query 'Per DM CLR: Please review this Condition and please note that this information is not reflected on the Childbearing Potential eCRF page. Please reconcile and update applicable details as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 11:49:10
User closed query 'Per DM query, kindly include surgical history of 'hysterectomy' to subject medical history in EDC. Thank you.' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 15:05:29
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Menopause related conditions, HLT: Menopausal effects NEC, PT: Artificial menopause, LLT: Surgical menopause - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 11:32:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 11:32:29
Query 'Per DM query, kindly include surgical history of 'hysterectomy' to subject medical history in EDC. Thank you.' answered with 'update' (Site from CRA).	Andryelle Toledo (b) (4)	20 Oct 2020 19:40:45
Query 'Per DM CLR: Please review this Condition and please note that this information is not reflected on the Childbearing Potential eCRF page. Please reconcile and update applicable details as appropriate. Otherwise, clarify. ' answered with 'update' (Site from DM).	Andryelle Toledo (b) (4)	20 Oct 2020 19:40:41
Data point term sent to Coder	System	20 Oct 2020 19:40:40
DataPoint Un-verified.	Andryelle Toledo (b) (4)	20 Oct 2020 19:40:24
Coding entries removed.	Andryelle Toledo (b) (4)	20 Oct 2020 19:40:24
User entered 'Surgical Post-Menopausal' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	20 Oct 2020 19:40:24
User opened query 'Per DM query, kindly include surgical history of 'hysterectomy' to subject medical history in EDC. Thank you.' (Site from CRA).	(b) (4), (b) (6)	13 Oct 2020 21:21:39
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:19:58

PRODUCTION RELEASE (v12.003
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745 of 4365

US3892032

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:18:29

[Condition](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review this Condition and please note that this information is not reflected on the Childbearing Potential eCRF page. Please reconcile and update applicable details as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 10:31:39
User closed query 'Per source it's noted that subject has acid reflux and bilateral dry eyes. Kindly add to EDC.' (Site from CRA).	(b) (4), (b) (6)	08 Oct 2020 20:18:28
Query 'Per source it's noted that subject has acid reflux and bilateral dry eyes. Kindly add to EDC.' answered with 'update' (Site from CRA).	Andryelle Toledo (b) (4)	01 Oct 2020 13:34:14
User opened query 'Per source it's noted that subject has acid reflux and bilateral dry eyes. Kindly add to EDC.' (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 21:50:43
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 17:00:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 17:00:52
Data point term sent to Coder	System	18 Sep 2020 17:00:20
User entered 'post menopausal'	Andryelle Toledo (b) (4)	18 Sep 2020 16:59:38

US3892032

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:29:27
DataPoint Un-verified.	Leslie Iverson (b) (4)	11 Nov 2020 21:12:12
User entered 'UN UNK 2000' reason for change:	(b) (4)	11 Nov 2020 21:12:12
Data Entry Error	Leslie Iverson (b) (4)	11 Nov 2020 21:12:12
DataPoint Verified.	(b) (4)	13 Oct 2020 21:19:58
User entered 'un UNK 2003'	(b) (4), (b) (6)	18 Sep 2020 16:59:38
	Andryelle Toledo (b) (4)	
	(b) (4)	

US3892032

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:19:58
User entered '0'	Andryelle Toledo (b) (4)	18 Sep 2020 16:59:38

US3892032

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:18:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:19:58
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	18 Sep 2020 16:59:38

US3892032

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:19:58
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	18 Sep 2020 16:59:38

US3892032

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:18:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:19:58
User entered '0'	Andryelle Toledo (b) (4)	18 Sep 2020 16:59:38

US3892032

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered 'Jan 2000'	System	11 Nov 2020 21:12:12
User entered 'Jan 2003'	System	18 Sep 2020 16:59:38

US3892032

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered '2000'	System	11 Nov 2020 21:12:12
User entered '2003'	System	18 Sep 2020 16:59:38

US3892032

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered empty.	System	18 Sep 2020 16:59:38

US3892032

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered empty.	System	18 Sep 2020 16:59:38

US3892032

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:18:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:47:42
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:56:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:56:56
Data point term sent to Coder	System	21 Dec 2020 21:55:57
DataPoint Un-verified.	Leslie Iverson (b) (4) (b) (4)	21 Dec 2020 21:55:49
Coding entries removed.	Leslie Iverson (b) (4) (b) (4)	21 Dec 2020 21:55:49
User entered 'Gastroesophageal reflux disease' reason for change: Data Entry Error	Leslie Iverson (b) (4) (b) (4)	21 Dec 2020 21:55:49
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:19:13
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 13:37:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 13:37:54
Data point term sent to Coder	System	01 Oct 2020 13:36:29
User entered 'Acid Reflux'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:35:44

US3892032

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:29:27
DataPoint Un-verified.	Andryelle Toledo (b) (4)	19 Nov 2020 23:18:35
User entered 'UN UNK 2019' reason for change:	(b) (4)	
Data Entry Error	Andryelle Toledo (b) (4)	19 Nov 2020 23:18:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 21:19:15
User entered 'un UNK 2009'	Andryelle Toledo (b) (4)	01 Oct 2020 13:35:44
	(b) (4)	

US3892032

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:19:33
User entered '0'	Andryelle Toledo (b) (4)	01 Oct 2020 13:35:44

US3892032

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:18:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:19:35
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	01 Oct 2020 13:35:44

US3892032

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:19:37
User entered empty.	Andryelle Toledo (b) (4)	01 Oct 2020 13:35:44

US3892032

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:18:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:19:39
User entered '0'	Andryelle Toledo (b) (4)	01 Oct 2020 13:35:44

US3892032

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered 'Jan 2019'	System	19 Nov 2020 23:18:35
User entered 'Jan 2009'	System	01 Oct 2020 13:35:44

US3892032

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered '2019'	System	19 Nov 2020 23:18:35
User entered '2009'	System	01 Oct 2020 13:35:44

US3892032

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered empty.	System	01 Oct 2020 13:35:44

US3892032

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered empty.	System	01 Oct 2020 13:35:44

US3892032

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:18:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:19:58
User coded data point as SOC: Eye disorders, HLGT: Eye disorders NEC, HLT: Lacrimation disorders, PT: Dry eye, LLT: Dry eyes - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 13:37:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 13:37:55
Data point term sent to Coder	System	01 Oct 2020 13:36:29
User entered 'bilateral dry eyes'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:36:05

US3892032

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:19:58
User entered 'un UNK 2018'	Andryelle Toledo (b) (4)	01 Oct 2020 13:36:05

US3892032

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:19:58
User entered '0'	Andryelle Toledo (b) (4)	01 Oct 2020 13:36:05

US3892032

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:18:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:19:58
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	01 Oct 2020 13:36:05

US3892032

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:19:58
User entered empty.	Andryelle Toledo (b) (4)	01 Oct 2020 13:36:05

US3892032

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:18:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:19:58
User entered '0'	Andryelle Toledo (b) (4)	01 Oct 2020 13:36:05

US3892032

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered 'Jan 2018'	System	01 Oct 2020 13:36:05

US3892032

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered '2018'	System	01 Oct 2020 13:36:05

US3892032

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered empty.	System	01 Oct 2020 13:36:05

US3892032

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered empty.	System	01 Oct 2020 13:36:05

US3892032

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:18:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:36:50
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 19:42:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 19:42:49
Data point term sent to Coder	System	20 Oct 2020 19:41:42
User entered 'Hysterectomy'	Andryelle Toledo (b) (4) (b) (4)	20 Oct 2020 19:41:22

US3892032

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:29:27
User closed query 'Per source hysterectomy is noted as the year 2000. Kindly confirm what data point is accurate and update accordingly. Thank you.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 22:02:29
Query 'Per source hysterectomy is noted as the year 2000. Kindly confirm what data point is accurate and update accordingly. Thank you.' answered with 'Correct date is year 2000.' (Site from CRA).	Leslie Iverson (b) (4) (b) (4)	11 Nov 2020 21:09:44
DataPoint Un-verified.	Leslie Iverson (b) (4) (b) (4)	11 Nov 2020 21:09:31
User entered 'UN UNK 2000' reason for change:	Leslie Iverson (b) (4)	11 Nov 2020 21:09:31
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:36:50
User opened query 'Per source hysterectomy is noted as the year 2000. Kindly confirm what data point is accurate and update accordingly. Thank you.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 18:48:11
User entered 'un UNK 2003'	Andryelle Toledo (b) (4) (b) (4)	20 Oct 2020 19:41:22

US3892032

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:36:50
User entered '0'	Andryelle Toledo (b) (4)	20 Oct 2020 19:41:22

US3892032

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:18:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:36:50
User entered 'No (N)'	Andryelle Toledo (b) (4)	20 Oct 2020 19:41:22

US3892032

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:29:27
User closed query 'Per source hysterectomy is noted as the year 2000. Kindly confirm what data point is accurate and update accordingly. Thank you.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 22:02:32
Query 'Per source hysterectomy is noted as the year 2000. Kindly confirm what data point is accurate and update accordingly. Thank you.' answered with 'Correct date is year 2000.' (Site from CRA).	Leslie Iverson (b) (4)	11 Nov 2020 21:09:54
DataPoint Un-verified.	Leslie Iverson (b) (4)	11 Nov 2020 21:09:31
User entered 'UN UNK 2000' reason for change:	Leslie Iverson (b) (4)	11 Nov 2020 21:09:31
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:36:50
User opened query 'Per source hysterectomy is noted as the year 2000. Kindly confirm what data point is accurate and update accordingly. Thank you.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 18:48:20
User entered 'un UNK 2003'	Andryelle Toledo (b) (4)	20 Oct 2020 19:41:22

US3892032

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:18:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:36:50
User entered '0'	Andryelle Toledo (b) (4)	20 Oct 2020 19:41:22

US3892032

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered 'Jan 2000'	System	11 Nov 2020 21:09:31
User entered 'Jan 2003'	System	20 Oct 2020 19:41:22

US3892032

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered '2000'	System	11 Nov 2020 21:09:31
User entered '2003'	System	20 Oct 2020 19:41:22

US3892032

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered 'Jan 2000'	System	11 Nov 2020 21:09:31
User entered 'Jan 2003'	System	20 Oct 2020 19:41:22

US3892032

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered '2000'	System	11 Nov 2020 21:09:31
User entered '2003'	System	20 Oct 2020 19:41:22

US3892032

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:18:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:45:39
User closed query 'Per DM CLR: Please specify the location and/or type of PERIPHERAL EDEMA. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 17:44:49
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Edema of lower extremities - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Jan 2021 06:49:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Jan 2021 06:49:19
Query 'Per DM CLR: Please specify the location and/or type of PERIPHERAL EDEMA. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'has been updated' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 23:03:52
Data point term sent to Coder	System	21 Jan 2021 22:56:14
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 22:55:28
Coding entries removed.	(b) (4), (b) (6)	21 Jan 2021 22:55:28
User entered 'PERIPHERAL EDEMA (bilateral-lower extremity)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 22:55:28
User opened query 'Per DM CLR: Please specify the location and/or type of PERIPHERAL EDEMA. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 04:27:40
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:29:27

US3892032

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:18:29

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Peripheral edema - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 23:20:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 23:20:52
Data point term sent to Coder	System	19 Nov 2020 23:19:21
User entered 'peripheral edema'	Andryelle Toledo (b) (4)	19 Nov 2020 23:19:16
	(b) (4)	

US3892032

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:45:43
User closed query 'Start date is after date of Informed System Consent. Please correct.' (Site from System).		21 Jan 2021 23:02:50
User entered 'UN UNK 1990' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 23:02:50
User opened query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	21 Jan 2021 22:58:02
User closed query 'Start date is after date of Informed System Consent. Please correct.' (Site from System).		21 Jan 2021 22:58:02
User entered '21 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 22:58:02
User opened query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	21 Jan 2021 22:55:28
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 22:55:28
User entered '27 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 22:55:28
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:29:27
User entered 'un UNK 1990'	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 23:19:16

US3892032

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:29:27
User entered '0'	Andryelle Toledo (b) (4)	19 Nov 2020 23:19:16

US3892032

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:18:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:29:27
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	19 Nov 2020 23:19:16

US3892032

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:29:27
User entered empty.	Andryelle Toledo (b) (4)	19 Nov 2020 23:19:16

US3892032

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:18:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:29:27
User entered '0'	Andryelle Toledo (b) (4)	19 Nov 2020 23:19:16

US3892032

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered 'Jan 1990'	System	21 Jan 2021 23:02:50
User entered 'Oct 2020'	System	21 Jan 2021 22:55:28
User entered 'Jan 1990'	System	19 Nov 2020 23:19:16

US3892032

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered '1990'	System	21 Jan 2021 23:02:50
User entered '2020'	System	21 Jan 2021 22:55:28
User entered '1990'	System	19 Nov 2020 23:19:16

US3892032

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered empty.	System	19 Nov 2020 23:19:16

US3892032

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered empty.	System	19 Nov 2020 23:19:16

US3892032

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:18:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:29:27
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Generalized osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 23:36:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 23:36:53
Data point term sent to Coder	System	19 Nov 2020 23:21:22
User entered 'GENERALIZED OSTEOARTHRITIS' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 23:20:50
Data point term sent to Coder	System	19 Nov 2020 23:20:22
User entered 'Generalizes Osteoarthritis'	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 23:20:00

US3892032

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:29:27
User entered 'un UNK 2000'	Andryelle Toledo (b) (4)	19 Nov 2020 23:20:00

US3892032

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:29:27
User entered '0'	Andryelle Toledo (b) (4)	19 Nov 2020 23:20:00

US3892032

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:18:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:29:27
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	19 Nov 2020 23:20:00

US3892032

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:29:27
User entered empty.	Andryelle Toledo (b) (4)	19 Nov 2020 23:20:00

US3892032

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:18:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:29:27
User entered '0'	Andryelle Toledo (b) (4)	19 Nov 2020 23:20:00

US3892032

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered 'Jan 2000'	System	19 Nov 2020 23:20:00

US3892032

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered '2000'	System	19 Nov 2020 23:20:00

US3892032

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered empty.	System	19 Nov 2020 23:20:00

US3892032

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered empty.	System	19 Nov 2020 23:20:00

US3892032

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:18:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:29:27
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal stenosis and obstruction, HLT: Oesophageal stenosis and obstruction, PT: Oesophageal stenosis, LLT: Esophageal stricture - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 23:21:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 23:21:53
Data point term sent to Coder	System	19 Nov 2020 23:21:22
User entered 'Esophageal stricture'	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 23:20:24

US3892032

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:29:27
User entered 'un UNK 2018'	Andryelle Toledo (b) (4)	19 Nov 2020 23:20:24

US3892032

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:29:27
User entered '0'	Andryelle Toledo (b) (4)	19 Nov 2020 23:20:24

US3892032

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:18:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:29:27
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	19 Nov 2020 23:20:24

US3892032

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:29:27
User entered empty.	Andryelle Toledo (b) (4)	19 Nov 2020 23:20:24

US3892032

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:18:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User closed query 'Kindly update MH with hx reason of "Radiesse" use. TThank you.' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 15:25:42
Query 'Kindly update MH with hx reason of "Radiesse" use. TThank you.' answered with 'update' (Site from CRA).	Andryelle Toledo (b) (4)	23 Mar 2021 14:53:39
User opened query 'Kindly update MH with hx reason of "Radiesse" use. TThank you.' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 19:15:32
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:29:27
User entered '0'	Andryelle Toledo (b) (4)	19 Nov 2020 23:20:24

US3892032

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered 'Jan 2018'	System	19 Nov 2020 23:20:24

US3892032

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered '2018'	System	19 Nov 2020 23:20:24

US3892032

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered empty.	System	19 Nov 2020 23:20:24

US3892032

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered empty.	System	19 Nov 2020 23:20:24

US3892032

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:18:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:17:42
User signature succeeded.	Michael Adams (b) (4)	29 Mar 2021 17:51:24
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin and subcutaneous tissue therapeutic procedures NEC, PT: Dermal filler injection, LLT: Dermal filler injection - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 07:06:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 07:06:39
Data point term sent to Coder	System	23 Mar 2021 14:54:51
User entered 'Use of Radiesse facial filler for cosmetic use'	Andryelle Toledo (b) (4)	23 Mar 2021 14:54:23

US3892032

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:17:50
User signature succeeded.	Michael Adams (b) (4)	29 Mar 2021 17:51:24
User entered 'un UNK 2019'	Andryelle Toledo (b) (4)	23 Mar 2021 14:54:23

US3892032

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:17:47
User signature succeeded.	Michael Adams (b) (4)	29 Mar 2021 17:51:24
User entered '0'	Andryelle Toledo (b) (4)	23 Mar 2021 14:54:23

US3892032

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:18:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:17:52
User signature succeeded.	Michael Adams (b) (4)	29 Mar 2021 17:51:24
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	23 Mar 2021 14:54:23

US3892032

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:17:53
User signature succeeded.	Michael Adams (b) (4)	29 Mar 2021 17:51:24
User entered 'un UNK 2019'	Andryelle Toledo (b) (4)	23 Mar 2021 14:54:23

US3892032

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:18:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:17:56
User signature succeeded.	Michael Adams (b) (4)	29 Mar 2021 17:51:24
User entered '0'	Andryelle Toledo (b) (4)	23 Mar 2021 14:54:23

US3892032

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered 'Jan 2019'	System	23 Mar 2021 14:54:23

US3892032

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:18:29

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered '2019'	System	23 Mar 2021 14:54:23

US3892032

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered 'Jan 2019'	System	23 Mar 2021 14:54:23

US3892032

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered '2019'	System	23 Mar 2021 14:54:23

US3892032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:06:58
User entered 'Yes (Y)'	chase Carnahan (b) (4)	31 Aug 2020 18:15:25

US3892032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:06:58
User entered '31 Aug 2020'	chase Carnahan (b) (4)	31 Aug 2020 18:15:25

US3892032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:06:58
User entered '10:44'	chase Carnahan (b) (4)	31 Aug 2020 18:15:25

US3892032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered '31 Aug 2020 10:44'	System	31 Aug 2020 18:15:25

US3892032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:06:58
User entered '161' cm	chase Carnahan (b) (4)	31 Aug 2020 18:15:25
DataPoint set to visible.	(b) (4) System	31 Aug 2020 18:14:33

US3892032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:06:58
User entered '109.4' kg	chase Carnahan (b) (4)	31 Aug 2020 18:15:25
DataPoint set to visible.	(b) (4) System	31 Aug 2020 18:14:33

US3892032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered '42.20516'	System	31 Aug 2020 18:15:25
DataPoint set to visible.	System	31 Aug 2020 18:14:33

US3892032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered 'kg/m2'	System	31 Aug 2020 18:15:25
DataPoint set to visible.	System	31 Aug 2020 18:14:33

US3892032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:06:58
User entered missing code ND - Not Done; reason for change Data Entry Error	Andryelle Toledo (b) (4)	03 Sep 2020 15:49:10
User entered '97.1' F	(b) (4) chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:15:25

US3892032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:06:58
User entered empty; reason for change Data Entry Error	Andryelle Toledo (b) (4)	03 Sep 2020 15:49:10
User entered 'Oral (Oral)'	(b) (4) chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:15:25

US3892032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:06:58
User entered empty.	chase Carnahan (b) (4)	31 Aug 2020 18:15:25

US3892032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:06:58
User entered missing code ND - Not Done; reason for change Data Entry Error	Andryelle Toledo (b) (4)	03 Sep 2020 15:49:10
User entered '71'	(b) (4) chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:15:25

US3892032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered 'bpm'	System	31 Aug 2020 18:15:25

US3892032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:06:58
User entered missing code ND - Not Done; reason for change Data Entry Error	Andryelle Toledo (b) (4)	03 Sep 2020 15:49:10
User entered '16'	(b) (4) chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:15:25

US3892032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered 'breaths/min'	System	31 Aug 2020 18:15:25

US3892032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:06:58
User entered missing code ND - Not Done; reason for change Data Entry Error	Andryelle Toledo (b) (4)	03 Sep 2020 15:49:10
User entered '130'	(b) (4) chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:15:25

US3892032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered 'mmHg'	System	31 Aug 2020 18:15:25

US3892032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:06:58
User entered missing code ND - Not Done; reason for change Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	03 Sep 2020 15:49:10
User entered '88'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:15:25

US3892032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User entered 'mmHg'	System	31 Aug 2020 18:15:25

US3892032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40

US3892032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40

US3892032

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:18:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:05:31
User entered 'Yes (Y)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:15:34

US3892032

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:18:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:05:31
User entered '31 Aug 2020'	chase Carnahan (b) (4)	31 Aug 2020 18:15:34

US3892032

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:18:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:03:02
User entered '31 Aug 2020'	chase Carnahan (b) (4)	31 Aug 2020 18:15:49

US3892032

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:03:02
User entered 'No (N)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:15:49

US3892032

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:18:29

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
User closed query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 11:44:02
Query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate.' answered with 'update' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	20 Oct 2020 19:39:48
User opened query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 04:19:20
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:03:02
User closed query 'Is the participant of childbearing potential is No, however reason is missing. Please provide.' (Site from System).	System	31 Aug 2020 18:15:59
User entered 'Surgically sterile (SURGICALLY STERILE)' reason for change: Data Entry Error	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:15:59
User opened query 'Is the participant of childbearing potential is No, however reason is missing. Please provide.' (Site from System).	System	31 Aug 2020 18:15:49
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:15:49

US3892032

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:18:29

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:03:02
User entered empty.	chase Carnahan (b) (4)	31 Aug 2020 18:15:49

US3892032

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:03:02
User closed query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	System	10 Sep 2020 22:02:22
User entered 'un UNK 2000' reason for change: Data Entry Error	Stefanie Vasconez (b) (4) (b) (4)	10 Sep 2020 22:02:22
User opened query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	System	31 Aug 2020 18:15:59
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:15:49

US3892032

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:18:29

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:03:02
User entered '0'	chase Carnahan (b) (4)	31 Aug 2020 18:15:49

US3892032

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:03:02
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:15:49

US3892032

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:18:29

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:03:02
User entered '0'	chase Carnahan (b) (4)	31 Aug 2020 18:15:49

US3892032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:04:07
User entered 'No (N)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:16:34

US3892032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:04:07
User entered 'No (N)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:16:34

US3892032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:29

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)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:04:07
User entered 'No (N)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:16:34

US3892032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:29

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)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:04:07
User entered 'No (N)'	chase Carnahan (b) (4)	31 Aug 2020 18:16:34

US3892032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:04:07
User entered 'No (N)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:16:34

US3892032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:29

[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)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:04:07
User entered 'No (N)'	chase Carnahan (b) (4)	31 Aug 2020 18:16:34

US3892032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:29

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)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:04:07
User entered 'No (N)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:16:34

US3892032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:29

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)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:04:07
User entered 'No (N)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:16:34

US3892032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:29

[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)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:04:07
User entered 'No (N)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:16:34

US3892032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:29

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)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:04:07
User entered 'No (N)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:16:34

US3892032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:29

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)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:04:07
User entered 'No (N)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:16:34

US3892032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:29

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:04:07
User entered 'Yes (Y)'	chase Carnahan (b) (4)	31 Aug 2020 18:16:34

US3892032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:29

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:04:07
User entered 'retired'	chase Carnahan (b) (4)	31 Aug 2020 18:16:34

US3892032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:29

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
User entered '0'	chase Carnahan (b) (4)	31 Aug 2020 18:16:34

US3892032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:04:07
User entered '0'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:16:34

US3892032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:29

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)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:04:07
User entered 'I'	chase Carnahan (b) (4)	31 Aug 2020 18:16:34

US3892032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:29

[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)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:04:07
User entered '0'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:16:34

US3892032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:29

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)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:04:07
User entered '0'	chase Carnahan (b) (4)	31 Aug 2020 18:16:34

US3892032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:04:07
User entered '0'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:16:34

US3892032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:29

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
User entered '0'	chase Carnahan (b) (4)	31 Aug 2020 18:16:34

US3892032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:18:29

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:02:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:04:07
User entered empty.	chase Carnahan (b) (4)	31 Aug 2020 18:16:34

US3892032

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 15:59:35
User entered 'Yes (Y)'	chase Carnahan (b) (4)	31 Aug 2020 18:13:42

US3892032

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 15:59:35
User entered '31 Aug 2020'	chase Carnahan (b) (4)	31 Aug 2020 18:13:42

US3892032

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:59:35
User entered 'Clinic (Clinic)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:13:42

US3892032

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered 'VISIT1'	System	31 Aug 2020 18:13:42

US3892032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:20:27
User entered '31 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 17:29:59

US3892032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:18:29

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:20:27
User entered '145452'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 17:29:59

US3892032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:20:27
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 17:29:59

US3892032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:18:29

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)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:20:27
User entered 'No (N)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:13:26

US3892032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:18:29

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)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:20:27
User entered 'No (N)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:13:26

US3892032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:18:29

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:20:27
User entered 'Yes (Y)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:13:26

US3892032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:18:29

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:20:27
User entered 'No (N)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:13:26

US3892032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:18:29

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:20:27
User entered 'No (N)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:13:26

US3892032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:18:29

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:46:59
User entered 'No (N)'	Stefanie Vasconez (b) (4) (b) (4)	21 Sep 2020 19:38:50
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:44:33
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:44:32

US3892032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:18:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:16:12
User entered missing code ND - Not Done; reason for change Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	03 Sep 2020 15:50:22
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:55:50

US3892032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:18:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:16:12
User entered missing code ND - Not Done; reason for change Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	03 Sep 2020 15:50:22
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:55:50

US3892032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:18:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:16:12
User entered missing code ND - Not Done; reason for change Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	03 Sep 2020 15:50:22
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:55:50

US3892032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:18:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:16:12
User entered missing code ND - Not Done; reason for change Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	03 Sep 2020 15:50:22
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:55:50

US3892032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User accepted default value 'Pre-Dose (PREDOSE)'	chase Carnahan (b) (4)	31 Aug 2020 21:55:50
	(b) (4)	

US3892032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:16:12
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 15:50:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 15:50:22
User entered 'Yes (Y)' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	03 Sep 2020 15:50:22
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 21:55:50
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:55:50

US3892032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:16:12
User entered '31 Aug 2020' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	03 Sep 2020 15:50:22
User entered empty.	(b) (4) chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:55:50

US3892032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:16:12
User entered '10:44' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	03 Sep 2020 15:50:22
User entered empty.	(b) (4) chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:55:50

US3892032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered '31 Aug 2020 10:44'	System	03 Sep 2020 15:50:22
User entered empty.	System	31 Aug 2020 21:55:50

US3892032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:16:12
User entered '97.1' F reason for change: Data Entry Error	Andryelle Toledo (b) (4)	03 Sep 2020 15:50:22
User entered empty.	(b) (4) chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:55:50

US3892032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:16:12
User entered 'Oral (Oral)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	03 Sep 2020 15:50:22
User entered empty.	(b) (4) chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:55:50

US3892032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:16:12
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:55:50

US3892032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:16:12
User entered '71' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	03 Sep 2020 15:50:22
User entered empty.	(b) (4) chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:55:50

US3892032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered 'bpm'	System	03 Sep 2020 15:50:22
User entered empty.	System	31 Aug 2020 21:55:50

US3892032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:16:12
User entered '16' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	03 Sep 2020 15:50:22
User entered empty.	(b) (4) chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:55:50

US3892032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered 'breaths/min'	System	03 Sep 2020 15:50:22
User entered empty.	System	31 Aug 2020 21:55:50

US3892032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:16:12
User entered '130' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	03 Sep 2020 15:50:22
User entered empty.	(b) (4) chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:55:50

US3892032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered 'mmHg'	System	03 Sep 2020 15:50:22
User entered empty.	System	31 Aug 2020 21:55:50

US3892032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:16:12
User entered '88' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	03 Sep 2020 15:50:22
User entered empty.	(b) (4) chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:55:50

US3892032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered 'mmHg'	System	03 Sep 2020 15:50:22
User entered empty.	System	31 Aug 2020 21:55:50

US3892032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:18:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:16:12
User entered missing code ND - Not Done; reason for change Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	03 Sep 2020 15:50:22
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:55:50

US3892032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:18:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:16:12
User entered missing code ND - Not Done; reason for change Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	03 Sep 2020 15:50:22
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:55:50

US3892032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User accepted default value 'Post-Dose (POSTDOSE)'	chase Carnahan (b) (4)	31 Aug 2020 21:55:50

US3892032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:16:12
User entered 'Yes (Y)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:55:50

US3892032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:16:12
User entered '31 Aug 2020'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:55:50

US3892032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:16:12
User entered '12:35'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:55:50

US3892032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered '31 Aug 2020 12:35'	System	31 Aug 2020 21:55:50

US3892032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:16:12
User entered '97.1' F	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:55:50

US3892032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:16:12
User entered 'Oral (Oral)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:55:50

US3892032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:16:12
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:55:50

US3892032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:16:12
User entered '71'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:55:50

US3892032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered 'bpm'	System	31 Aug 2020 21:55:50

US3892032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:16:12
User entered '16'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:55:50

US3892032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered 'breaths/min'	System	31 Aug 2020 21:55:50

US3892032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:16:12
User entered '121'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:55:50

US3892032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered 'mmHg'	System	31 Aug 2020 21:55:50

US3892032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:16:12
User entered '82'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:55:50

US3892032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered 'mmHg'	System	31 Aug 2020 21:55:50

US3892032

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:18:29

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:33:49
User closed query 'Per eCRF guidelines, this should be noted as "No". Also, kindly delete date of exam. Thank you.' (Site from CRA).	(b) (4), (b) (6)	18 Sep 2020 21:15:12
Query 'Per eCRF guidelines, this should be noted as "No". Also, kindly delete date of exam. Thank you.' answered with 'update' (Site from CRA).	Andryelle Toledo (b) (4)	18 Sep 2020 16:38:04
DataPoint Un-verified.	(b) (4)	
	Andryelle Toledo (b) (4)	18 Sep 2020 16:37:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	18 Sep 2020 16:37:57
User opened query 'Per eCRF guidelines, this should be noted as "No". Also, kindly delete date of exam. Thank you.' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 16:20:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:17:25
User entered 'Yes (Y)'	chase Carnahan (b) (4)	31 Aug 2020 18:19:00
	(b) (4)	

US3892032

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:18:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:33:49
DataPoint Un-verified.	Andryelle Toledo (b) (4)	18 Sep 2020 16:37:57
User entered empty; reason for change Data Entry Error	(b) (4) Andryelle Toledo (b) (4)	18 Sep 2020 16:37:57
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:17:25
User entered '31 Aug 2020'	chase Carnahan (b) (4)	31 Aug 2020 18:19:00
	(b) (4)	

US3892032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:18:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:23:14
User entered 'Yes (Y)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:17:16

US3892032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:18:29

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:23:14
User entered empty.	chase Carnahan (b) (4)	31 Aug 2020 18:17:16

US3892032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:18:29

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)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:23:14
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:17:16

US3892032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:18:29

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered 'MRNA-1273 OR PLACEBO'	System	31 Aug 2020 18:17:16

US3892032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:18:29

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:23:14
User entered '31 Aug 2020'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:17:16

US3892032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:23:14
User entered '12:02'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:17:16

US3892032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered '31 Aug 2020 12:02'	System	31 Aug 2020 18:17:16

US3892032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:34:58
DataPoint Un-verified.	(b) (4), (b) (6)	18 Sep 2020 21:02:33
User closed query 'Kindly confirm this arm is correct, as in subject source notes, this is blank. Thank you.' (Site from CRA).	(b) (4), (b) (6)	18 Sep 2020 21:02:31
Query 'Kindly confirm this arm is correct, as in subject source notes, this is blank. Thank you.' answered with 'Confirm ' (Site from CRA).	Andryelle Toledo (b) (4) (b) (4)	18 Sep 2020 17:00:25
User opened query 'Kindly confirm this arm is correct, as in subject source notes, this is blank. Thank you.' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 16:24:28
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:23:14
User entered 'Left Arm (LEFT ARM)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:17:16

US3892032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:23:14
User entered 'ONCE'	System	31 Aug 2020 18:17:16

US3892032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:18:29

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered 'INTRAMUSCULAR'	System	31 Aug 2020 18:17:16

US3892032

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:59:45
User entered 'Yes (Y)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:16:53

US3892032

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 15:59:45
User entered '31 Aug 2020'	chase Carnahan (b) (4)	31 Aug 2020 18:16:53

US3892032

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:59:45
User entered '11:50'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:16:53

US3892032

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered '31 Aug 2020 11:50'	System	31 Aug 2020 18:16:53

US3892032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:18:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:17:04
User entered '31 Aug 2020'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:18:32

US3892032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:18:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	chase Carnahan (b) (4)	31 Aug 2020 18:18:32

US3892032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:18:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:17:04
User entered 'Yes (Y)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:18:32

US3892032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:18:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:17:04
User entered '11:30'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:18:32

US3892032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered '31 Aug 2020 11:30'	System	31 Aug 2020 18:18:32

US3892032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:18:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	chase Carnahan (b) (4)	31 Aug 2020 18:18:32

US3892032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:18:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:17:04
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 18:18:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 18:18:40
User entered 'No (N)' reason for change: Data Entry Error	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:18:40
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 18:18:32
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:18:32

US3892032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:18:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:17:04
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:18:32

US3892032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:18:29

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered empty.	System	31 Aug 2020 18:18:32

US3892032

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:59:50
User entered 'Yes (Y)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 18:18:46

US3892032

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:18:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered 'I'	System	31 Aug 2020 18:18:46

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	31 Aug 2020 18:17:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-08-31T12:36:10', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'f5ddb09a-7c05-4612-a9af-5b29f7a52fa2' User entered 'Yes (Y)'	System	31 Aug 2020 18:36:38
	System	31 Aug 2020 18:36:38

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-08-31T12:36:19', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'f5ddb09a-7c05-4612-a9af-5b29f7a52fa2' User entered '97.1'	System	31 Aug 2020 18:36:38
	System	31 Aug 2020 18:36:38

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-08-31T12:36:29', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'f5ddb09a-7c05-4612-a9af-5b29f7a52fa2'	System	31 Aug 2020 18:36:38
User entered 'No (N)'	System	31 Aug 2020 18:36:38

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-08-31T12:36:36', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'f5ddb09a-7c05-4612-a9af-5b29f7a52fa2'	System	31 Aug 2020 18:36:38
User entered '31 Aug 2020 12:36'	System	31 Aug 2020 18:36:38

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '31 Aug 2020 12:22'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '31 Aug 2020 14:52'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	31 Aug 2020 18:17:16
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-08-31T19:49:01', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'dad0eab6-7011-4b96-9e93-274cd11dce77'	System	01 Sep 2020 01:49:32
User entered 'Yes (Y)'	System	01 Sep 2020 01:49:32

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-08-31T19:49:09', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'dad0eab6-7011-4b96-9e93-274cd11dce77'	System	01 Sep 2020 01:49:32
User entered '97.8'	System	01 Sep 2020 01:49:32

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-08-31T19:49:13', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'dad0eab6-7011-4b96-9e93-274cd11dce77'	System	01 Sep 2020 01:49:32
User entered 'No (N)'	System	01 Sep 2020 01:49:32

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-08-31T19:49:30', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'dad0eab6-7011-4b96-9e93-274cd11dce77'	System	01 Sep 2020 01:49:32
User entered '31 Aug 2020 19:49'	System	01 Sep 2020 01:49:32

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '31 Aug 2020 15:47'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	31 Aug 2020 18:17:16
User entered 'Day 2'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:18:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:18:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:18:29

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	31 Aug 2020 18:17:16
User entered 'Day 3'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:18:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-02T20:09:50', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '674a6e24-e783-4945-b8fa-4ffa831c4039'	System	03 Sep 2020 02:10:20
User entered 'Yes (Y)'	System	03 Sep 2020 02:10:20

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:18:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-02T20:10:01', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '674a6e24-e783-4945-b8fa-4ffa831c4039' User entered '97.4'	System	03 Sep 2020 02:10:20
	System	03 Sep 2020 02:10:20

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-02T20:10:05', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '674a6e24-e783-4945-b8fa-4ffa831c4039'	System	03 Sep 2020 02:10:20
User entered 'No (N)'	System	03 Sep 2020 02:10:20

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-02T20:10:19', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '674a6e24-e783-4945-b8fa-4ffa831c4039'	System	03 Sep 2020 02:10:20
User entered '02 Sep 2020 20:10'	System	03 Sep 2020 02:10:20

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	31 Aug 2020 18:17:16
User entered 'Day 4'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:18:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-03T21:18:59', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '8683c75e-252a-4aa8-8842-6d9a5c647fa7'	System	04 Sep 2020 03:19:30
User entered 'Yes (Y)'	System	04 Sep 2020 03:19:30

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:18:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-03T21:19:07', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '8683c75e-252a-4aa8-8842-6d9a5c647fa7' User entered '97.1'	System	04 Sep 2020 03:19:30
	System	04 Sep 2020 03:19:30

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-03T21:19:12', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '8683c75e-252a-4aa8-8842-6d9a5c647fa7'	System	04 Sep 2020 03:19:30
User entered 'No (N)'	System	04 Sep 2020 03:19:30

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-03T21:19:27', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '8683c75e-252a-4aa8-8842-6d9a5c647fa7'	System	04 Sep 2020 03:19:30
User entered '03 Sep 2020 21:19'	System	04 Sep 2020 03:19:30

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	31 Aug 2020 18:17:16
User entered 'Day 5'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:18:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-04T20:19:31', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '283214f9-419b-4dd5-a3e8-66175782e839'	System	05 Sep 2020 02:19:54
User entered 'Yes (Y)'	System	05 Sep 2020 02:19:54

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:18:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-04T20:19:38', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '283214f9-419b-4dd5-a3e8-66175782e839' User entered '98.6'	System	05 Sep 2020 02:19:54
	System	05 Sep 2020 02:19:54

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-04T20:19:42', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '283214f9-419b-4dd5-a3e8-66175782e839'	System	05 Sep 2020 02:19:54
User entered 'No (N)'	System	05 Sep 2020 02:19:54

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-04T20:19:52', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '283214f9-419b-4dd5-a3e8-66175782e839'	System	05 Sep 2020 02:19:54
User entered '04 Sep 2020 20:19'	System	05 Sep 2020 02:19:54

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	31 Aug 2020 18:17:16
User entered 'Day 6'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:18:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-06T02:32:53', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'f731204f-c4cb-4ba3-90e9-c43724d7c050'	System	06 Sep 2020 08:34:23
User entered 'Yes (Y)'	System	06 Sep 2020 08:34:23

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:18:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-06T02:33:59', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'f731204f-c4cb-4ba3-90e9-c43724d7c050' User entered '98.6'	System	06 Sep 2020 08:34:23
	System	06 Sep 2020 08:34:23

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-06T02:34:03', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'f731204f-c4cb-4ba3-90e9-c43724d7c050'	System	06 Sep 2020 08:34:23
User entered 'No (N)'	System	06 Sep 2020 08:34:23

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-06T02:34:16', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'f731204f-c4cb-4ba3-90e9-c43724d7c050'	System	06 Sep 2020 08:34:23
User entered '06 Sep 2020 02:34'	System	06 Sep 2020 08:34:23

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	31 Aug 2020 18:17:16
User entered 'Day 7'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:18:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-06T20:09:46', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '19c0a98a-5dc6-4e79-bbea-a711034baf76' User entered 'Yes (Y)'	System	07 Sep 2020 02:10:30
	System	07 Sep 2020 02:10:30

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:18:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-06T20:10:18', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '19c0a98a-5dc6-4e79-bbea-a711034baf76' User entered '97.2'	System	07 Sep 2020 02:10:30
	System	07 Sep 2020 02:10:30

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-06T20:10:21', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '19c0a98a-5dc6-4e79-bbea-a711034baf76'	System	07 Sep 2020 02:10:30
User entered 'No (N)'	System	07 Sep 2020 02:10:30

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-06T20:10:28', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '19c0a98a-5dc6-4e79-bbea-a711034baf76' User entered '06 Sep 2020 20:10'	System	07 Sep 2020 02:10:30
	System	07 Sep 2020 02:10:30

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	31 Aug 2020 18:17:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-08-31T12:36:47', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'a79f4a33-1a18-4cc8-9941-3a90c3e2e9cd'	System	31 Aug 2020 18:37:18
User entered 'None (1)'	System	31 Aug 2020 18:37:18

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-08-31T12:36:58', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'a79f4a33-1a18-4cc8-9941-3a90c3e2e9cd'	System	31 Aug 2020 18:37:18
User entered 'No (N)'	System	31 Aug 2020 18:37:18

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-08-31T12:37:01', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'a79f4a33-1a18-4cc8-9941-3a90c3e2e9cd' User entered 'No (N)'	System	31 Aug 2020 18:37:18
	System	31 Aug 2020 18:37:18

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-08-31T12:37:12', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'a79f4a33-1a18-4cc8-9941-3a90c3e2e9cd' User entered 'None (1)'	System	31 Aug 2020 18:37:18
	System	31 Aug 2020 18:37:18

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-08-31T12:37:17', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'a79f4a33-1a18-4cc8-9941-3a90c3e2e9cd'	System	31 Aug 2020 18:37:18
User entered '31 Aug 2020 12:37'	System	31 Aug 2020 18:37:18

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '31 Aug 2020 12:22'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '31 Aug 2020 14:52'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	31 Aug 2020 18:17:16
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-08-31T19:49:45', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '9da7f660-805e-40cc-ac56-79c46cdbbeac'	System	01 Sep 2020 01:50:17
User entered 'None (1)'	System	01 Sep 2020 01:50:17

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-08-31T19:49:49', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '9da7f660-805e-40cc-ac56-79c46cdbbeac'	System	01 Sep 2020 01:50:17
User entered 'No (N)'	System	01 Sep 2020 01:50:17

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-08-31T19:49:53', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '9da7f660-805e-40cc-ac56-79c46cdbbeac'	System	01 Sep 2020 01:50:17
User entered 'No (N)'	System	01 Sep 2020 01:50:17

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-08-31T19:50:04', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '9da7f660-805e-40cc-ac56-79c46cdbbeac'	System	01 Sep 2020 01:50:17
User entered 'None (1)'	System	01 Sep 2020 01:50:17

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-08-31T19:50:12', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '9da7f660-805e-40cc-ac56-79c46cdbbeac'	System	01 Sep 2020 01:50:17
User entered '31 Aug 2020 19:50'	System	01 Sep 2020 01:50:17

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '31 Aug 2020 15:47'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	31 Aug 2020 18:17:16
User entered 'Day 2'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:18:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	31 Aug 2020 18:17:16
User entered 'Day 3'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-02T20:10:32', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '15c1e8b5-23d6-4e12-8d1c-bc133249f550'	System	03 Sep 2020 02:10:59
User entered 'None (1)'	System	03 Sep 2020 02:10:59

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:18:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-02T20:10:36', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '15c1e8b5-23d6-4e12-8d1c-bc133249f550'	System	03 Sep 2020 02:10:59
User entered 'No (N)'	System	03 Sep 2020 02:10:59

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-02T20:10:41', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '15c1e8b5-23d6-4e12-8d1c-bc133249f550'	System	03 Sep 2020 02:10:59
User entered 'No (N)'	System	03 Sep 2020 02:10:59

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-02T20:10:46', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '15c1e8b5-23d6-4e12-8d1c-bc133249f550'	System	03 Sep 2020 02:10:59
User entered 'None (1)'	System	03 Sep 2020 02:10:59

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-02T20:10:57', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '15c1e8b5-23d6-4e12-8d1c-bc133249f550'	System	03 Sep 2020 02:10:59
User entered '02 Sep 2020 20:10'	System	03 Sep 2020 02:10:59

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	31 Aug 2020 18:17:16
User entered 'Day 4'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-03T21:19:40', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7253e79c-c503-4a23-823c-f293e767711f' User entered 'None (1)'	System	04 Sep 2020 03:20:13
	System	04 Sep 2020 03:20:13

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:18:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-03T21:19:49', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7253e79c-c503-4a23-823c-f293e767711f' User entered 'No (N)'	System	04 Sep 2020 03:20:13
	System	04 Sep 2020 03:20:13

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-03T21:19:54', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7253e79c-c503-4a23-823c-f293e767711f' User entered 'No (N)'	System	04 Sep 2020 03:20:13
	System	04 Sep 2020 03:20:13

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-03T21:19:59', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7253e79c-c503-4a23-823c-f293e767711f' User entered 'None (1)'	System	04 Sep 2020 03:20:13
	System	04 Sep 2020 03:20:13

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-03T21:20:12', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7253e79c-c503-4a23-823c-f293e767711f' User entered '03 Sep 2020 21:20'	System	04 Sep 2020 03:20:13
	System	04 Sep 2020 03:20:13

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	31 Aug 2020 18:17:16
User entered 'Day 5'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-04T20:19:57', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '63fdc9df-0134-4928-b613-a24f758030f9' User entered 'None (1)'	System	05 Sep 2020 02:20:37
	System	05 Sep 2020 02:20:37

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:18:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-04T20:20:02', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '63fdc9df-0134-4928-b613-a24f758030f9'	System	05 Sep 2020 02:20:37
User entered 'No (N)'	System	05 Sep 2020 02:20:37

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-04T20:20:08', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '63fdc9df-0134-4928-b613-a24f758030f9'	System	05 Sep 2020 02:20:37
User entered 'No (N)'	System	05 Sep 2020 02:20:37

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-04T20:20:24', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '63fdc9df-0134-4928-b613-a24f758030f9' User entered 'None (1)'	System	05 Sep 2020 02:20:37
	System	05 Sep 2020 02:20:37

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-04T20:20:34', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '63fdc9df-0134-4928-b613-a24f758030f9' User entered '04 Sep 2020 20:20'	System	05 Sep 2020 02:20:37
	System	05 Sep 2020 02:20:37

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	31 Aug 2020 18:17:16
User entered 'Day 6'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-06T02:34:24', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '1a07533f-7f74-433e-9ce5-a5b4ea0f4709'	System	06 Sep 2020 08:34:56
User entered 'None (1)'	System	06 Sep 2020 08:34:56

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:18:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-06T02:34:29', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '1a07533f-7f74-433e-9ce5-a5b4ea0f4709'	System	06 Sep 2020 08:34:56
User entered 'No (N)'	System	06 Sep 2020 08:34:56

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-06T02:34:35', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '1a07533f-7f74-433e-9ce5-a5b4ea0f4709' User entered 'No (N)'	System	06 Sep 2020 08:34:56
	System	06 Sep 2020 08:34:56

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-06T02:34:42', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '1a07533f-7f74-433e-9ce5-a5b4ea0f4709'	System	06 Sep 2020 08:34:56
User entered 'None (1)'	System	06 Sep 2020 08:34:56

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-06T02:34:51', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '1a07533f-7f74-433e-9ce5-a5b4ea0f4709' User entered '06 Sep 2020 02:34'	System	06 Sep 2020 08:34:56
	System	06 Sep 2020 08:34:56

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	31 Aug 2020 18:17:16
User entered 'Day 7'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-06T20:10:33', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '0538b9c0-d2ef-44fe-abab-a92fa30edfb7'	System	07 Sep 2020 02:10:52
User entered 'None (1)'	System	07 Sep 2020 02:10:52

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:18:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-06T20:10:37', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '0538b9c0-d2ef-44fe-abab-a92fa30edfb7' User entered 'No (N)'	System	07 Sep 2020 02:10:52
	System	07 Sep 2020 02:10:52

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-06T20:10:40', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '0538b9c0-d2ef-44fe-abab-a92fa30edfb7' User entered 'No (N)'	System	07 Sep 2020 02:10:52
	System	07 Sep 2020 02:10:52

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-06T20:10:44', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '0538b9c0-d2ef-44fe-abab-a92fa30edfb7' User entered 'None (1)'	System	07 Sep 2020 02:10:52
	System	07 Sep 2020 02:10:52

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-06T20:10:49', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '0538b9c0-d2ef-44fe-abab-a92fa30edfb7' User entered '06 Sep 2020 20:10'	System	07 Sep 2020 02:10:52
	System	07 Sep 2020 02:10:52

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	31 Aug 2020 18:17:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-08-31T12:37:22', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'e9b32c71-ca68-49c4-b3f3-4ff546e9865c' User entered 'None (0)'	System	31 Aug 2020 18:37:52
	System	31 Aug 2020 18:37:52

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-08-31T12:37:27', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'e9b32c71-ca68-49c4-b3f3-4ff546e9865c' User entered 'None (0)'	System	31 Aug 2020 18:37:52
	System	31 Aug 2020 18:37:52

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-08-31T12:37:31', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'e9b32c71-ca68-49c4-b3f3-4ff546e9865c' User entered 'None (0)'	System	31 Aug 2020 18:37:52
	System	31 Aug 2020 18:37:52

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-08-31T12:37:34', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'e9b32c71-ca68-49c4-b3f3-4ff546e9865c' User entered 'None (0)'	System	31 Aug 2020 18:37:52
	System	31 Aug 2020 18:37:52

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-08-31T12:37:37', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'e9b32c71-ca68-49c4-b3f3-4ff546e9865c' User entered 'None (0)'	System	31 Aug 2020 18:37:52
	System	31 Aug 2020 18:37:52

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-08-31T12:37:41', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'e9b32c71-ca68-49c4-b3f3-4ff546e9865c' User entered 'None (0)'	System	31 Aug 2020 18:37:52
	System	31 Aug 2020 18:37:52

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-08-31T12:37:45', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'e9b32c71-ca68-49c4-b3f3-4ff546e9865c' User entered 'No (N)'	System	31 Aug 2020 18:37:52
	System	31 Aug 2020 18:37:52

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-08-31T12:37:48', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'e9b32c71-ca68-49c4-b3f3-4ff546e9865c' User entered '31 Aug 2020 12:37'	System	31 Aug 2020 18:37:52
	System	31 Aug 2020 18:37:52

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '31 Aug 2020 12:22'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '31 Aug 2020 14:52'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	31 Aug 2020 18:17:16
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-08-31T19:50:20', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'ed0602e5-fd8e-4edb-9033-6b257634652c' User entered 'None (0)'	System	01 Sep 2020 01:51:13
	System	01 Sep 2020 01:51:13

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-08-31T19:50:31', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'ed0602e5-fd8e-4edb-9033-6b257634652c'	System	01 Sep 2020 01:51:13
User entered 'No interference with activity (1)'	System	01 Sep 2020 01:51:13

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-08-31T19:50:37', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'ed0602e5-fd8e-4edb-9033-6b257634652c' User entered 'None (0)'	System	01 Sep 2020 01:51:13
	System	01 Sep 2020 01:51:13

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-08-31T19:50:45', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'ed0602e5-fd8e-4edb-9033-6b257634652c' User entered 'None (0)'	System	01 Sep 2020 01:51:13
	System	01 Sep 2020 01:51:13

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-08-31T19:50:51', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'ed0602e5-fd8e-4edb-9033-6b257634652c' User entered 'None (0)'	System	01 Sep 2020 01:51:13
	System	01 Sep 2020 01:51:13

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-08-31T19:50:54', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'ed0602e5-fd8e-4edb-9033-6b257634652c' User entered 'None (0)'	System	01 Sep 2020 01:51:13
	System	01 Sep 2020 01:51:13

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-08-31T19:50:59', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'ed0602e5-fd8e-4edb-9033-6b257634652c' User entered 'No (N)'	System	01 Sep 2020 01:51:13
	System	01 Sep 2020 01:51:13

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-08-31T19:51:12', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'ed0602e5-fd8e-4edb-9033-6b257634652c'	System	01 Sep 2020 01:51:13
User entered '31 Aug 2020 19:51'	System	01 Sep 2020 01:51:13

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '31 Aug 2020 15:47'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	31 Aug 2020 18:17:16
User entered 'Day 2'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	31 Aug 2020 18:17:16
User entered 'Day 3'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-02T20:11:04', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'c9152484-ef54-44bd-86b6-3bdaf5778503' User entered 'None (0)'	System	03 Sep 2020 02:11:44
	System	03 Sep 2020 02:11:44

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-02T20:11:14', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'c9152484-ef54-44bd-86b6-3bdaf5778503' User entered 'None (0)'	System	03 Sep 2020 02:11:44
	System	03 Sep 2020 02:11:44

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-02T20:11:18', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'c9152484-ef54-44bd-86b6-3bdaf5778503' User entered 'None (0)'	System	03 Sep 2020 02:11:44
	System	03 Sep 2020 02:11:44

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-02T20:11:23', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'c9152484-ef54-44bd-86b6-3bdaf5778503' User entered 'None (0)'	System	03 Sep 2020 02:11:44
	System	03 Sep 2020 02:11:44

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-02T20:11:27', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'c9152484-ef54-44bd-86b6-3bdaf5778503' User entered 'None (0)'	System	03 Sep 2020 02:11:44
	System	03 Sep 2020 02:11:44

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-02T20:11:31', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'c9152484-ef54-44bd-86b6-3bdaf5778503'	System	03 Sep 2020 02:11:44
User entered 'None (0)'	System	03 Sep 2020 02:11:44

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-02T20:11:36', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'c9152484-ef54-44bd-86b6-3bdaf5778503'	System	03 Sep 2020 02:11:44
User entered 'No (N)'	System	03 Sep 2020 02:11:44

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-02T20:11:42', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'c9152484-ef54-44bd-86b6-3bdaf5778503'	System	03 Sep 2020 02:11:44
User entered '02 Sep 2020 20:11'	System	03 Sep 2020 02:11:44

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	31 Aug 2020 18:17:16
User entered 'Day 4'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-03T21:20:20', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '8470c92e-0cf2-462c-9f40-cca9cd653b90' User entered 'None (0)'	System	04 Sep 2020 03:21:36
	System	04 Sep 2020 03:21:36

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-03T21:20:28', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '8470c92e-0cf2-462c-9f40-cca9cd653b90'	System	04 Sep 2020 03:21:36
User entered 'No interference with activity (1)'	System	04 Sep 2020 03:21:36

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-03T21:20:34', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '8470c92e-0cf2-462c-9f40-cca9cd653b90' User entered 'None (0)'	System	04 Sep 2020 03:21:36
	System	04 Sep 2020 03:21:36

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-03T21:20:41', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '8470c92e-0cf2-462c-9f40-cca9cd653b90' User entered 'None (0)'	System	04 Sep 2020 03:21:36
	System	04 Sep 2020 03:21:36

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-03T21:20:46', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '8470c92e-0cf2-462c-9f40-cca9cd653b90' User entered 'None (0)'	System	04 Sep 2020 03:21:36
	System	04 Sep 2020 03:21:36

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-03T21:20:50', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '8470c92e-0cf2-462c-9f40-cca9cd653b90' User entered 'None (0)'	System	04 Sep 2020 03:21:36
	System	04 Sep 2020 03:21:36

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-03T21:21:05', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '8470c92e-0cf2-462c-9f40-cca9cd653b90'	System	04 Sep 2020 03:21:36
User entered 'Yes (Y)'	System	04 Sep 2020 03:21:36

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-03T21:21:33', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '8470c92e-0cf2-462c-9f40-cca9cd653b90' User entered '03 Sep 2020 21:21'	System	04 Sep 2020 03:21:36
	System	04 Sep 2020 03:21:36

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	31 Aug 2020 18:17:16
User entered 'Day 5'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-04T20:20:39', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '14fb1025-8b98-4e03-af2b-27293886dd7b' User entered 'None (0)'	System	05 Sep 2020 02:21:17
	System	05 Sep 2020 02:21:17

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-04T20:20:43', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '14fb1025-8b98-4e03-af2b-27293886dd7b'	System	05 Sep 2020 02:21:17
User entered 'No interference with activity (1)'	System	05 Sep 2020 02:21:17

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-04T20:20:48', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '14fb1025-8b98-4e03-af2b-27293886dd7b' User entered 'None (0)'	System	05 Sep 2020 02:21:17
	System	05 Sep 2020 02:21:17

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-04T20:20:51', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '14fb1025-8b98-4e03-af2b-27293886dd7b' User entered 'None (0)'	System	05 Sep 2020 02:21:17
	System	05 Sep 2020 02:21:17

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-04T20:20:53', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '14fb1025-8b98-4e03-af2b-27293886dd7b' User entered 'None (0)'	System	05 Sep 2020 02:21:17
	System	05 Sep 2020 02:21:17

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-04T20:20:56', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '14fb1025-8b98-4e03-af2b-27293886dd7b' User entered 'None (0)'	System	05 Sep 2020 02:21:17
	System	05 Sep 2020 02:21:17

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-04T20:21:05', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '14fb1025-8b98-4e03-af2b-27293886dd7b' User entered 'No (N)'	System	05 Sep 2020 02:21:17
	System	05 Sep 2020 02:21:17

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-04T20:21:13', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '14fb1025-8b98-4e03-af2b-27293886dd7b' User entered '04 Sep 2020 20:21'	System	05 Sep 2020 02:21:17
	System	05 Sep 2020 02:21:17

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	31 Aug 2020 18:17:16
User entered 'Day 6'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-06T02:35:08', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '0c12cc70-9a39-48d3-8286-313864c7ed57' User entered 'None (0)'	System	06 Sep 2020 08:35:57
	System	06 Sep 2020 08:35:57

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-06T02:35:15', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '0c12cc70-9a39-48d3-8286-313864c7ed57'	System	06 Sep 2020 08:35:57
User entered 'No interference with activity (1)'	System	06 Sep 2020 08:35:57

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-06T02:35:21', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '0c12cc70-9a39-48d3-8286-313864c7ed57' User entered 'None (0)'	System	06 Sep 2020 08:35:57
	System	06 Sep 2020 08:35:57

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-06T02:35:25', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '0c12cc70-9a39-48d3-8286-313864c7ed57' User entered 'None (0)'	System	06 Sep 2020 08:35:57
	System	06 Sep 2020 08:35:57

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-06T02:35:30', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '0c12cc70-9a39-48d3-8286-313864c7ed57' User entered 'None (0)'	System	06 Sep 2020 08:35:57
	System	06 Sep 2020 08:35:57

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-06T02:35:36', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '0c12cc70-9a39-48d3-8286-313864c7ed57' User entered 'None (0)'	System	06 Sep 2020 08:35:57
	System	06 Sep 2020 08:35:57

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-06T02:35:48', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '0c12cc70-9a39-48d3-8286-313864c7ed57'	System	06 Sep 2020 08:35:57
User entered 'No (N)'	System	06 Sep 2020 08:35:57

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-06T02:35:55', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '0c12cc70-9a39-48d3-8286-313864c7ed57' User entered '06 Sep 2020 02:35'	System	06 Sep 2020 08:35:57
	System	06 Sep 2020 08:35:57

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	31 Aug 2020 18:17:16
User entered 'Day 7'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-06T20:11:31', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '71967162-ef14-4423-8f01-528b68467f50'	System	07 Sep 2020 02:12:30
User entered 'No interference with activity (1)'	System	07 Sep 2020 02:12:30

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-06T20:11:36', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '71967162-ef14-4423-8f01-528b68467f50'	System	07 Sep 2020 02:12:30
User entered 'Some interference with activity (2)'	System	07 Sep 2020 02:12:30

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-06T20:11:43', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '71967162-ef14-4423-8f01-528b68467f50'	System	07 Sep 2020 02:12:30
User entered 'Some interference with activity (2)'	System	07 Sep 2020 02:12:30

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-06T20:11:55', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '71967162-ef14-4423-8f01-528b68467f50'	System	07 Sep 2020 02:12:30
User entered 'No interference with activity (1)'	System	07 Sep 2020 02:12:30

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-06T20:12:04', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '71967162-ef14-4423-8f01-528b68467f50'	System	07 Sep 2020 02:12:30
User entered 'None (0)'	System	07 Sep 2020 02:12:30

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-06T20:12:15', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '71967162-ef14-4423-8f01-528b68467f50'	System	07 Sep 2020 02:12:30
User entered 'No interference with activity (1)'	System	07 Sep 2020 02:12:30

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-06T20:12:23', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '71967162-ef14-4423-8f01-528b68467f50'	System	07 Sep 2020 02:12:30
User entered 'No (N)'	System	07 Sep 2020 02:12:30

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-06T20:12:27', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '71967162-ef14-4423-8f01-528b68467f50'	System	07 Sep 2020 02:12:30
User entered '06 Sep 2020 20:12'	System	07 Sep 2020 02:12:30

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 18:17:16

US3892032

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	07 Sep 2020 02:12:30
User entered 'Day 8'	System	07 Sep 2020 02:12:30

US3892032

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-08T09:09:57', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '801c4373-dd76-4820-bfd7-e31262f87c40' User entered 'None (0)'	System	08 Sep 2020 15:10:13
	System	08 Sep 2020 15:10:13

US3892032

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-08T09:10:09', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '801c4373-dd76-4820-bfd7-e31262f87c40' User entered '08 Sep 2020 09:10'	System	08 Sep 2020 15:10:13
	System	08 Sep 2020 15:10:13

US3892032

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '07 Sep 2020 12:00'	System	07 Sep 2020 02:12:30

US3892032

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '08 Sep 2020 11:59'	System	07 Sep 2020 02:12:30

US3892032

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	06 Sep 2020 08:35:57
User entered 'Day 8'	System	06 Sep 2020 08:35:57

US3892032

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-08T09:10:24', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '658b1cec-3225-4e68-91a9-bb1ac60d285e'	System	08 Sep 2020 15:10:35
User entered 'No interference with activity (1)'	System	08 Sep 2020 15:10:35

US3892032

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-08T09:10:32', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '658b1cec-3225-4e68-91a9-bb1ac60d285e' User entered '08 Sep 2020 09:10'	System	08 Sep 2020 15:10:35
	System	08 Sep 2020 15:10:35

US3892032

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '07 Sep 2020 12:00'	System	06 Sep 2020 08:35:57

US3892032

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '08 Sep 2020 11:59'	System	06 Sep 2020 08:35:57

US3892032

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	07 Sep 2020 02:12:30
User entered 'Day 9'	System	07 Sep 2020 02:12:30

US3892032

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-08T19:24:20', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '55018593-0cac-4c47-926c-bda8abb8f5b2' User entered 'None (0)'	System	09 Sep 2020 01:24:28
	System	09 Sep 2020 01:24:28

US3892032

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-08T19:24:25', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '55018593-0cac-4c47-926c-bda8abb8f5b2' User entered '08 Sep 2020 19:24'	System	09 Sep 2020 01:24:28
	System	09 Sep 2020 01:24:28

US3892032

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 02:12:30

US3892032

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 02:12:30

US3892032

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	07 Sep 2020 02:12:30
User entered 'Day 8'	System	07 Sep 2020 02:12:30

US3892032

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 10:18:29

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-08T09:10:39', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '228dc0bc-a85d-415d-9c61-56c3a426f9c4' User entered 'None (0)'	System	08 Sep 2020 15:10:50
	System	08 Sep 2020 15:10:50

US3892032

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-08T09:10:46', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '228dc0bc-a85d-415d-9c61-56c3a426f9c4'	System	08 Sep 2020 15:10:50
User entered '08 Sep 2020 09:10'	System	08 Sep 2020 15:10:50

US3892032

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '07 Sep 2020 12:00'	System	07 Sep 2020 02:12:30

US3892032

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '08 Sep 2020 11:59'	System	07 Sep 2020 02:12:30

US3892032

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	07 Sep 2020 02:12:30
User entered 'Day 8'	System	07 Sep 2020 02:12:30

US3892032

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 10:18:29

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-08T09:10:52', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'f00837e6-ef8d-4c56-bb39-0d306af28ef6' User entered 'None (0)'	System	08 Sep 2020 15:11:08
	System	08 Sep 2020 15:11:08

US3892032

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-08T09:11:07', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'f00837e6-ef8d-4c56-bb39-0d306af28ef6' User entered '08 Sep 2020 09:11'	System	08 Sep 2020 15:11:08
	System	08 Sep 2020 15:11:08

US3892032

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '07 Sep 2020 12:00'	System	07 Sep 2020 02:12:30

US3892032

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '08 Sep 2020 11:59'	System	07 Sep 2020 02:12:30

US3892032

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	07 Sep 2020 02:12:30
User entered 'Day 8'	System	07 Sep 2020 02:12:30

US3892032

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 10:18:29

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-08T09:11:12', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'ad98030b-b4ca-48a4-8ee8-a847652cd805' User entered 'None (0)'	System	08 Sep 2020 15:11:23
	System	08 Sep 2020 15:11:23

US3892032

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '07 Sep 2020 12:00'	System	07 Sep 2020 02:12:30

US3892032

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '08 Sep 2020 11:59'	System	07 Sep 2020 02:12:30

US3892032

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-08T09:11:21', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'ad98030b-b4ca-48a4-8ee8-a847652cd805'	System	08 Sep 2020 15:11:23
User entered '08 Sep 2020 09:11'	System	08 Sep 2020 15:11:23

US3892032

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	06 Sep 2020 08:35:57
User entered 'Day 8'	System	06 Sep 2020 08:35:57

US3892032

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-08T09:11:35', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7550a403-499e-45c9-afbb-2bb03c28327c' User entered 'No (N)'	System	08 Sep 2020 15:11:44
	System	08 Sep 2020 15:11:44

US3892032

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-08T09:11:41', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7550a403-499e-45c9-afbb-2bb03c28327c' User entered '08 Sep 2020 09:11'	System	08 Sep 2020 15:11:44
	System	08 Sep 2020 15:11:44

US3892032

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '07 Sep 2020 12:00'	System	06 Sep 2020 08:35:57

US3892032

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '08 Sep 2020 11:59'	System	06 Sep 2020 08:35:57

US3892032

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:27:10
User entered 'Yes (Y)'	Stefanie Vasconez (b) (4)	07 Sep 2020 19:51:49

US3892032

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:27:10
User entered '7 Sep 2020'	Stefanie Vasconez (b) (4)	07 Sep 2020 19:51:49

US3892032

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:27:10
User entered 'Contact Made (CONTACT MADE)'	Stefanie Vasconez (b) (4) (b) (4)	07 Sep 2020 19:51:49

US3892032

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:27:10
User entered empty.	Stefanie Vasconez (b) (4)	07 Sep 2020 19:51:49

US3892032

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:27:01
User entered 'Yes (Y)'	Stefanie Vasconez (b) (4) (b) (4)	07 Sep 2020 19:51:56

US3892032

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered 'I'	System	07 Sep 2020 19:51:56

US3892032

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:28:46
User entered 'Yes (Y)'	Stefanie Vasconez (b) (4)	14 Sep 2020 16:31:51

US3892032

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:28:46
User entered '14 Sep 2020'	Stefanie Vasconez (b) (4)	14 Sep 2020 16:31:51

US3892032

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:28:46
User entered 'Contact Made (CONTACT MADE)'	Stefanie Vasconez (b) (4) (b) (4)	14 Sep 2020 16:31:51

US3892032

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:28:46
User entered empty.	Stefanie Vasconez (b) (4)	14 Sep 2020 16:31:51

US3892032

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:28:35
User entered 'Yes (Y)'	Stefanie Vasconez (b) (4) (b) (4)	14 Sep 2020 16:32:05

US3892032

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered 'I'	System	14 Sep 2020 16:32:05

US3892032

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:42:50
User entered 'Yes (Y)'	Stefanie Vasconez (b) (4) (b) (4)	21 Sep 2020 19:40:31

US3892032

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:42:50
User entered '21 Sep 2020'	Stefanie Vasconez (b) (4)	21 Sep 2020 19:40:31

US3892032

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:42:50
User entered 'Contact Made (CONTACT MADE)'	Stefanie Vasconez (b) (4) (b) (4)	21 Sep 2020 19:40:31

US3892032

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:42:50
User entered empty.	Stefanie Vasconez (b) (4) (b) (4)	21 Sep 2020 19:40:31

US3892032

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:41:54
User entered 'Yes (Y)'	Stefanie Vasconez (b) (4) (b) (4)	21 Sep 2020 19:40:35

US3892032

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered 'I'	System	21 Sep 2020 19:40:35

US3892032

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:23:10
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	28 Sep 2020 18:07:17

US3892032

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:23:10
User entered '28 Sep 2020'	Andryelle Toledo (b) (4) (b) (4)	28 Sep 2020 18:07:17

US3892032

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:23:10
User entered 'Clinic (Clinic)'	Andryelle Toledo (b) (4) (b) (4)	28 Sep 2020 18:07:17

US3892032

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered 'VISIT2'	System	28 Sep 2020 18:07:17

US3892032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User accepted default value 'Pre-Dose (PREDOSE)'	Andryelle Toledo (b) (4)	01 Oct 2020 13:44:49
	(b) (4)	

US3892032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:23:35
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:44:49

US3892032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:23:35
User entered '28 Sep 2020'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:44:49

US3892032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:23:35
User entered '10:38'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:44:49

US3892032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered '28 Sep 2020 10:38'	System	01 Oct 2020 13:44:49

US3892032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:23:35
User entered '98.3' F	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:44:49

US3892032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:23:35
User entered 'Oral (Oral)'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:44:49

US3892032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:23:35
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:44:49

US3892032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:23:35
User entered '82'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:44:49

US3892032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered 'bpm'	System	01 Oct 2020 13:44:49

US3892032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:23:35
User entered '14'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:44:49

US3892032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered 'breaths/min'	System	01 Oct 2020 13:44:49

US3892032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:23:35
User entered '135'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:44:49

US3892032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered 'mmHg'	System	01 Oct 2020 13:44:49

US3892032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:23:35
User entered '83'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:44:49

US3892032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered 'mmHg'	System	01 Oct 2020 13:44:49

US3892032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User accepted default value 'Post-Dose (POSTDOSE)'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:44:49

US3892032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:23:35
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:44:49

US3892032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:23:35
User entered '28 Sep 2020'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:44:49

US3892032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:23:35
User entered '12:27'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:44:49

US3892032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered '28 Sep 2020 12:27'	System	01 Oct 2020 13:44:49

US3892032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:23:35
User entered '97.4' F	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:44:49

US3892032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:23:35
User entered 'Oral (Oral)'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:44:49

US3892032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:23:35
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:44:49

US3892032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:23:35
User entered '65'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:44:49

US3892032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered 'bpm'	System	01 Oct 2020 13:44:49

US3892032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:23:35
User entered '14'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:44:49

US3892032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered 'breaths/min'	System	01 Oct 2020 13:44:49

US3892032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:23:35
User entered '132'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:44:49

US3892032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered 'mmHg'	System	01 Oct 2020 13:44:49

US3892032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:23:35
User entered '88'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:44:49

US3892032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered 'mmHg'	System	01 Oct 2020 13:44:49

US3892032

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:18:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:26:31
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:46:05

US3892032

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:18:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:26:31
User entered '28 Sep 2020'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:46:05

US3892032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:18:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:26:48
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	28 Sep 2020 18:07:40

US3892032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:18:29

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:26:48
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	28 Sep 2020 18:07:40

US3892032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:18:29

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)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:26:48
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	28 Sep 2020 18:07:40

US3892032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:18:29

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered 'MRNA-1273 OR PLACEBO'	System	28 Sep 2020 18:07:40

US3892032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:18:29

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:26:48
User entered '28 Sep 2020'	Andryelle Toledo (b) (4) (b) (4)	28 Sep 2020 18:07:40

US3892032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:26:48
User entered '11:52'	Andryelle Toledo (b) (4) (b) (4)	28 Sep 2020 18:07:40

US3892032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered '28 Sep 2020 11:52'	System	28 Sep 2020 18:07:40

US3892032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:26:48
User entered 'Left Arm (LEFT ARM)'	Andryelle Toledo (b) (4) (b) (4)	28 Sep 2020 18:07:40

US3892032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:26:48
User entered 'ONCE'	System	28 Sep 2020 18:07:40

US3892032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:18:29

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered 'INTRAMUSCULAR'	System	28 Sep 2020 18:07:40

US3892032

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:27:31
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:46:27

US3892032

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:27:31
User entered '28 Sep 2020'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:46:27

US3892032

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:27:31
User entered '11:07'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:46:27

US3892032

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered '28 Sep 2020 11:07'	System	01 Oct 2020 13:46:27

US3892032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:18:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:26:21
User entered '28 Sep 2020'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:46:49

US3892032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:18:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:46:49

US3892032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:18:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:26:21
User entered 'Yes (Y)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	13 Oct 2020 18:19:36
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:46:49

US3892032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:18:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:26:21
User entered '11:13' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	13 Oct 2020 18:19:36
User entered empty.	(b) (4) Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:46:49

US3892032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered '28 Sep 2020 11:13'	System	13 Oct 2020 18:19:36
User entered empty.	System	01 Oct 2020 13:46:49

US3892032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:18:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Andryelle Toledo (b) (4)	01 Oct 2020 13:46:49

US3892032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:18:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:26:21
User entered 'No (N)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	13 Oct 2020 18:19:36
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:46:49

US3892032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:18:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:26:21
User entered empty; reason for change Data Entry Error	Andryelle Toledo (b) (4)	13 Oct 2020 18:19:36
User entered '11:13'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:46:49

US3892032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered empty.	System	13 Oct 2020 18:19:36
User entered '28 Sep 2020 11:13'	System	01 Oct 2020 13:46:49

US3892032

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:24:58
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:47:09

US3892032

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered 'I'	System	01 Oct 2020 13:47:09

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	28 Sep 2020 18:07:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-28T12:30:32', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '53dcdf31-c53e-4bbf-8f9b-0eef7ff50a3f' User entered 'Yes (Y)'	System	28 Sep 2020 18:30:57
	System	28 Sep 2020 18:30:57

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-28T12:30:45', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '53dcdf31-c53e-4bbf-8f9b-0eef7ff50a3f' User entered '97.4'	System	28 Sep 2020 18:30:57
	System	28 Sep 2020 18:30:57

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-28T12:30:48', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '53dcdf31-c53e-4bbf-8f9b-0eef7ff50a3f'	System	28 Sep 2020 18:30:57
User entered 'No (N)'	System	28 Sep 2020 18:30:57

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-28T12:30:54', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '53dcdf31-c53e-4bbf-8f9b-0eef7ff50a3f' User entered '28 Sep 2020 12:30'	System	28 Sep 2020 18:30:57
	System	28 Sep 2020 18:30:57

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '28 Sep 2020 12:12'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '28 Sep 2020 14:42'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	28 Sep 2020 18:07:40
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-28T21:26:10', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '09eff3a7-5ffa-4fb5-90f5-43518c2c7758'	System	29 Sep 2020 03:26:32
User entered 'Yes (Y)'	System	29 Sep 2020 03:26:32

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-28T21:26:17', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '09eff3a7-5ffa-4fb5-90f5-43518c2c7758'	System	29 Sep 2020 03:26:32
User entered '98.6'	System	29 Sep 2020 03:26:32

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-28T21:26:24', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '09eff3a7-5ffa-4fb5-90f5-43518c2c7758'	System	29 Sep 2020 03:26:32
User entered 'No (N)'	System	29 Sep 2020 03:26:32

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-28T21:26:31', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '09eff3a7-5ffa-4fb5-90f5-43518c2c7758'	System	29 Sep 2020 03:26:32
User entered '28 Sep 2020 21:26'	System	29 Sep 2020 03:26:32

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '28 Sep 2020 15:37'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	28 Sep 2020 18:07:40
User entered 'Day 2'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:18:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-29T20:01:36', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'b695da22-f9d2-40c7-834b-05c3e9678395'	System	30 Sep 2020 02:04:56
User entered 'Yes (Y)'	System	30 Sep 2020 02:04:56

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:18:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-29T20:04:16', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'b695da22-f9d2-40c7-834b-05c3e9678395' User entered '98.0'	System	30 Sep 2020 02:04:56
	System	30 Sep 2020 02:04:56

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-29T20:04:22', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'b695da22-f9d2-40c7-834b-05c3e9678395'	System	30 Sep 2020 02:04:56
User entered 'Yes (Y)'	System	30 Sep 2020 02:04:56

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject took Theraflu. Medication update.' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 05:41:30
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-29T20:04:37', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'b695da22-f9d2-40c7-834b-05c3e9678395' User entered '1'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 21:53:12
	System	30 Sep 2020 02:04:56
	System	30 Sep 2020 02:04:56
	System	30 Sep 2020 02:04:56

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:18:29

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-29T20:04:37', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'b695da22-f9d2-40c7-834b-05c3e9678395' User entered '0'	System	30 Sep 2020 02:04:56
	System	30 Sep 2020 02:04:56

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-29T20:04:54', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'b695da22-f9d2-40c7-834b-05c3e9678395' User entered '29 Sep 2020 20:04'	System	30 Sep 2020 02:04:56
	System	30 Sep 2020 02:04:56

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	28 Sep 2020 18:07:40
User entered 'Day 3'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:18:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-01T04:04:04', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '6685c8a7-89be-4942-9a0a-4924de264c64' User entered 'Yes (Y)'	System	01 Oct 2020 10:05:14
	System	01 Oct 2020 10:05:14

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:18:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-01T04:04:24', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '6685c8a7-89be-4942-9a0a-4924de264c64' User entered '98.0'	System	01 Oct 2020 10:05:14
	System	01 Oct 2020 10:05:14

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-01T04:04:32', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '6685c8a7-89be-4942-9a0a-4924de264c64'	System	01 Oct 2020 10:05:14
User entered 'Yes (Y)'	System	01 Oct 2020 10:05:14

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject took Theraflu. Medication update.' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 05:41:42
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-01T04:04:43', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '6685c8a7-89be-4942-9a0a-4924de264c64' User entered '1'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 21:53:27
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	01 Oct 2020 10:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-01T04:04:43', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '6685c8a7-89be-4942-9a0a-4924de264c64' User entered '1'	System	01 Oct 2020 10:05:14
User entered '1'	System	01 Oct 2020 10:05:14

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:18:29

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-01T04:04:43', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '6685c8a7-89be-4942-9a0a-4924de264c64' User entered '0'	System	01 Oct 2020 10:05:14
	System	01 Oct 2020 10:05:14

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-01T04:04:47', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '6685c8a7-89be-4942-9a0a-4924de264c64' User entered '01 Oct 2020 04:04'	System	01 Oct 2020 10:05:14
	System	01 Oct 2020 10:05:14

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	28 Sep 2020 18:07:40
User entered 'Day 4'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:18:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-02T00:14:06', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'cfcaca6f-c452-4331-835f-2adf9e097d77'	System	02 Oct 2020 06:16:45
User entered 'Yes (Y)'	System	02 Oct 2020 06:16:45

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:18:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-02T00:16:32', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'cfcaca6f-c452-4331-835f-2adf9e097d77' User entered '97.4'	System	02 Oct 2020 06:16:45
	System	02 Oct 2020 06:16:45

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-02T00:16:36', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'cfcaca6f-c452-4331-835f-2adf9e097d77'	System	02 Oct 2020 06:16:45
User entered 'Yes (Y)'	System	02 Oct 2020 06:16:45

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject took Theraflu. Medication update.' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 05:42:00
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-02T00:16:40', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'cfcaca6f-c452-4331-835f-2adf9e097d77'	Andryelle Toledo (b) (4)	21 Oct 2020 21:53:44
User entered '1'	System	02 Oct 2020 06:16:45
	System	02 Oct 2020 06:16:45
	System	02 Oct 2020 06:16:45

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:18:29

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-02T00:16:40', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'cfcaca6f-c452-4331-835f-2adf9e097d77'	System	02 Oct 2020 06:16:45
User entered '0'	System	02 Oct 2020 06:16:45

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-02T00:16:44', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'cfcaca6f-c452-4331-835f-2adf9e097d77'	System	02 Oct 2020 06:16:45
User entered '02 Oct 2020 00:16'	System	02 Oct 2020 06:16:45

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	28 Sep 2020 18:07:40
User entered 'Day 5'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:18:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-03T00:40:24', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '6b749cfc-8883-41f2-9680-d350e0cca000' User entered 'Yes (Y)'	System	03 Oct 2020 06:40:50
	System	03 Oct 2020 06:40:50

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:18:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-03T00:40:31', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '6b749cfc-8883-41f2-9680-d350e0cca000' User entered '98.4'	System	03 Oct 2020 06:40:50
	System	03 Oct 2020 06:40:50

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-03T00:40:35', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '6b749cfc-8883-41f2-9680-d350e0cca000'	System	03 Oct 2020 06:40:50
User entered 'Yes (Y)'	System	03 Oct 2020 06:40:50

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject took Theraflu. Medication update.' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 05:42:14
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-03T00:40:40', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '6b749cfc-8883-41f2-9680-d350e0cca000' User entered '1'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 21:53:53
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	03 Oct 2020 06:40:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-03T00:40:40', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '6b749cfc-8883-41f2-9680-d350e0cca000' User entered '1'	System	03 Oct 2020 06:40:50
User entered '1'	System	03 Oct 2020 06:40:50

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:18:29

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-03T00:40:40', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '6b749cfc-8883-41f2-9680-d350e0cca000' User entered '0'	System	03 Oct 2020 06:40:50
	System	03 Oct 2020 06:40:50

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-03T00:40:48', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '6b749cfc-8883-41f2-9680-d350e0cca000' User entered '03 Oct 2020 00:40'	System	03 Oct 2020 06:40:50
	System	03 Oct 2020 06:40:50

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	28 Sep 2020 18:07:40
User entered 'Day 6'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:18:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-03T22:21:44', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'e907181b-12cd-47b3-bd2e-ceb9959a4679' User entered 'Yes (Y)'	System	04 Oct 2020 04:22:47
	System	04 Oct 2020 04:22:47

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:18:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-03T22:22:35', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'e907181b-12cd-47b3-bd2e-ceb9959a4679' User entered '98.1'	System	04 Oct 2020 04:22:47
	System	04 Oct 2020 04:22:47

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-03T22:22:39', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'e907181b-12cd-47b3-bd2e-ceb9959a4679'	System	04 Oct 2020 04:22:47
User entered 'Yes (Y)'	System	04 Oct 2020 04:22:47

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject took Theraflu. Medication update.' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 05:44:43
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-03T22:22:42', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'e907181b-12cd-47b3-bd2e-ceb9959a4679' User entered '1'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 21:54:03
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	04 Oct 2020 04:22:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-03T22:22:42', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'e907181b-12cd-47b3-bd2e-ceb9959a4679' User entered '1'	System	04 Oct 2020 04:22:47
User entered '1'	System	04 Oct 2020 04:22:47

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:18:29

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-03T22:22:42', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'e907181b-12cd-47b3-bd2e-ceb9959a4679' User entered '0'	System	04 Oct 2020 04:22:47
	System	04 Oct 2020 04:22:47

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-03T22:22:45', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'e907181b-12cd-47b3-bd2e-ceb9959a4679' User entered '03 Oct 2020 22:22'	System	04 Oct 2020 04:22:47
	System	04 Oct 2020 04:22:47

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	28 Sep 2020 18:07:40
User entered 'Day 7'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:18:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-04T20:28:38', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'a433533e-e036-42b6-9a22-40e55c8be01a' User entered 'Yes (Y)'	System	05 Oct 2020 02:29:53
	System	05 Oct 2020 02:29:53

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:18:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-04T20:29:38', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'a433533e-e036-42b6-9a22-40e55c8be01a' User entered '97.8'	System	05 Oct 2020 02:29:53
	System	05 Oct 2020 02:29:53

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-04T20:29:42', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'a433533e-e036-42b6-9a22-40e55c8be01a'	System	05 Oct 2020 02:29:53
User entered 'Yes (Y)'	System	05 Oct 2020 02:29:53

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject took Theraflu. Medication update.' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 05:44:54
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-04T20:29:45', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'a433533e-e036-42b6-9a22-40e55c8be01a' User entered '1'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 21:54:14
	System	05 Oct 2020 02:29:53
	System	05 Oct 2020 02:29:53
	System	05 Oct 2020 02:29:53

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:18:29

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-04T20:29:45', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'a433533e-e036-42b6-9a22-40e55c8be01a' User entered '0'	System	05 Oct 2020 02:29:53
	System	05 Oct 2020 02:29:53

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-04T20:29:50', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'a433533e-e036-42b6-9a22-40e55c8be01a' User entered '04 Oct 2020 20:29'	System	05 Oct 2020 02:29:53
	System	05 Oct 2020 02:29:53

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	04 Oct 2020 04:22:47
User entered 'Day 8'	System	04 Oct 2020 04:22:47

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 10:18:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-05T23:54:17', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '361e32c2-874f-4a6a-9845-2571088a7089' User entered 'Yes (Y)'	System	06 Oct 2020 05:55:15
	System	06 Oct 2020 05:55:15

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 10:18:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-05T23:54:34', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '361e32c2-874f-4a6a-9845-2571088a7089' User entered '96.9'	System	06 Oct 2020 05:55:15
	System	06 Oct 2020 05:55:15

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-05T23:54:38', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '361e32c2-874f-4a6a-9845-2571088a7089'	System	06 Oct 2020 05:55:15
User entered 'Yes (Y)'	System	06 Oct 2020 05:55:15

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject took Theraflu. Medication update.' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 05:45:10
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-05T23:55:07', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '361e32c2-874f-4a6a-9845-2571088a7089' User entered '1'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 21:54:22
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	06 Oct 2020 05:55:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-05T23:55:07', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '361e32c2-874f-4a6a-9845-2571088a7089' User entered '1'	System	06 Oct 2020 05:55:15
User entered '1'	System	06 Oct 2020 05:55:15

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 10:18:29

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-05T23:55:07', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '361e32c2-874f-4a6a-9845-2571088a7089' User entered '0'	System	06 Oct 2020 05:55:15
	System	06 Oct 2020 05:55:15

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-05T23:55:12', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '361e32c2-874f-4a6a-9845-2571088a7089' User entered '05 Oct 2020 23:55'	System	06 Oct 2020 05:55:15
	System	06 Oct 2020 05:55:15

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 04:22:47

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 04:22:47

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	05 Oct 2020 02:29:53
User entered 'Day 9'	System	05 Oct 2020 02:29:53

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 10:18:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-06T23:28:59', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'a078e5a8-af58-4411-8e1e-ee8ae80e71c5' User entered 'Yes (Y)'	System	07 Oct 2020 05:31:31
	System	07 Oct 2020 05:31:31

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 10:18:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-06T23:31:07', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'a078e5a8-af58-4411-8e1e-ee8ae80e71c5'	System	07 Oct 2020 05:31:31
User entered '95.6'	System	07 Oct 2020 05:31:31

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-06T23:31:17', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'a078e5a8-af58-4411-8e1e-ee8ae80e71c5'	System	07 Oct 2020 05:31:31
User entered 'Yes (Y)'	System	07 Oct 2020 05:31:31

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject took Theraflu. Medication update.' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 05:45:15
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-06T23:31:20', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'a078e5a8-af58-4411-8e1e-ee8ae80e71c5' User entered '1'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 21:54:32
	System	07 Oct 2020 05:31:31
	System	07 Oct 2020 05:31:31
	System	07 Oct 2020 05:31:31

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 10:18:29

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-06T23:31:20', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'a078e5a8-af58-4411-8e1e-ee8ae80e71c5' User entered '0'	System	07 Oct 2020 05:31:31
	System	07 Oct 2020 05:31:31

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-06T23:31:26', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'a078e5a8-af58-4411-8e1e-ee8ae80e71c5' User entered '06 Oct 2020 23:31'	System	07 Oct 2020 05:31:31
	System	07 Oct 2020 05:31:31

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 02:29:53

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 02:29:53

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	06 Oct 2020 05:55:15
User entered 'Day 10'	System	06 Oct 2020 05:55:15

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 10:18:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-08T00:21:40', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'bb15e3a4-b427-4d3e-8e4e-5336386f32de' User entered 'Yes (Y)'	System	08 Oct 2020 06:22:00
	System	08 Oct 2020 06:22:00

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 10:18:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-08T00:21:47', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'bb15e3a4-b427-4d3e-8e4e-5336386f32de' User entered '96.4'	System	08 Oct 2020 06:22:00
	System	08 Oct 2020 06:22:00

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-08T00:21:51', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'bb15e3a4-b427-4d3e-8e4e-5336386f32de'	System	08 Oct 2020 06:22:00
User entered 'No (N)'	System	08 Oct 2020 06:22:00

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-08T00:21:57', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'bb15e3a4-b427-4d3e-8e4e-5336386f32de' User entered '08 Oct 2020 00:21'	System	08 Oct 2020 06:22:00
	System	08 Oct 2020 06:22:00

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 05:55:15

US3892032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 05:55:15

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	28 Sep 2020 18:07:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-28T12:31:01', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'b2893af8-67dd-4e32-9bfc-82835f4a8f1e'	System	28 Sep 2020 18:31:50
User entered 'None (1)'	System	28 Sep 2020 18:31:50

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-28T12:31:25', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'b2893af8-67dd-4e32-9bfc-82835f4a8f1e' User entered 'No (N)'	System	28 Sep 2020 18:31:50
	System	28 Sep 2020 18:31:50

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-28T12:31:29', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'b2893af8-67dd-4e32-9bfc-82835f4a8f1e' User entered 'No (N)'	System	28 Sep 2020 18:31:50
	System	28 Sep 2020 18:31:50

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-28T12:31:41', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'b2893af8-67dd-4e32-9bfc-82835f4a8f1e' User entered 'None (1)'	System	28 Sep 2020 18:31:50
	System	28 Sep 2020 18:31:50

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-28T12:31:47', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'b2893af8-67dd-4e32-9bfc-82835f4a8f1e' User entered '28 Sep 2020 12:31'	System	28 Sep 2020 18:31:50
	System	28 Sep 2020 18:31:50

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '28 Sep 2020 12:12'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '28 Sep 2020 14:42'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	28 Sep 2020 18:07:40
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-28T21:26:40', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'a7eda9ad-8571-4302-975f-e1e7b63bdccb' User entered 'None (1)'	System	29 Sep 2020 03:27:15
	System	29 Sep 2020 03:27:15

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-28T21:26:44', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'a7eda9ad-8571-4302-975f-e1e7b63bdccb' User entered 'No (N)'	System	29 Sep 2020 03:27:15
	System	29 Sep 2020 03:27:15

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-28T21:27:03', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'a7eda9ad-8571-4302-975f-e1e7b63bdccb' User entered 'No (N)'	System	29 Sep 2020 03:27:15
	System	29 Sep 2020 03:27:15

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-28T21:27:10', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'a7eda9ad-8571-4302-975f-e1e7b63bdccb' User entered 'None (1)'	System	29 Sep 2020 03:27:15
	System	29 Sep 2020 03:27:15

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-28T21:27:13', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'a7eda9ad-8571-4302-975f-e1e7b63bdccb' User entered '28 Sep 2020 21:27'	System	29 Sep 2020 03:27:15
	System	29 Sep 2020 03:27:15

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '28 Sep 2020 15:37'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	28 Sep 2020 18:07:40
User entered 'Day 2'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-29T20:05:01', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '84bf859e-08c1-48ff-81ef-364f5ccd8cbe'	System	30 Sep 2020 02:05:35
User entered 'None (1)'	System	30 Sep 2020 02:05:35

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:18:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-29T20:05:05', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '84bf859e-08c1-48ff-81ef-364f5ccd8cbe'	System	30 Sep 2020 02:05:35
User entered 'No (N)'	System	30 Sep 2020 02:05:35

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-29T20:05:11', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '84bf859e-08c1-48ff-81ef-364f5ccd8cbe' User entered 'No (N)'	System	30 Sep 2020 02:05:35
	System	30 Sep 2020 02:05:35

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-29T20:05:21', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '84bf859e-08c1-48ff-81ef-364f5ccd8cbe' User entered 'None (1)'	System	30 Sep 2020 02:05:35
	System	30 Sep 2020 02:05:35

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-29T20:05:32', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '84bf859e-08c1-48ff-81ef-364f5ccd8cbe' User entered '29 Sep 2020 20:05'	System	30 Sep 2020 02:05:35
	System	30 Sep 2020 02:05:35

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	28 Sep 2020 18:07:40
User entered 'Day 3'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-01T04:04:58', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '48912e58-d6cc-44c9-b70f-5c1948435179' User entered 'None (1)'	System	01 Oct 2020 10:05:34
	System	01 Oct 2020 10:05:34

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:18:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-01T04:05:15', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '48912e58-d6cc-44c9-b70f-5c1948435179' User entered 'No (N)'	System	01 Oct 2020 10:05:34
	System	01 Oct 2020 10:05:34

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-01T04:05:20', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '48912e58-d6cc-44c9-b70f-5c1948435179' User entered 'No (N)'	System	01 Oct 2020 10:05:34
	System	01 Oct 2020 10:05:34

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-01T04:05:24', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '48912e58-d6cc-44c9-b70f-5c1948435179' User entered 'None (1)'	System	01 Oct 2020 10:05:34
	System	01 Oct 2020 10:05:34

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-01T04:05:32', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '48912e58-d6cc-44c9-b70f-5c1948435179' User entered '01 Oct 2020 04:05'	System	01 Oct 2020 10:05:34
	System	01 Oct 2020 10:05:34

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	28 Sep 2020 18:07:40
User entered 'Day 4'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-02T00:16:49', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'dde515a4-9731-425b-81fc-1928e2fc0173'	System	02 Oct 2020 06:17:07
User entered 'None (1)'	System	02 Oct 2020 06:17:07

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:18:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-02T00:16:53', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'dde515a4-9731-425b-81fc-1928e2fc0173' User entered 'No (N)'	System	02 Oct 2020 06:17:07
	System	02 Oct 2020 06:17:07

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-02T00:16:55', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'dde515a4-9731-425b-81fc-1928e2fc0173' User entered 'No (N)'	System	02 Oct 2020 06:17:07
	System	02 Oct 2020 06:17:07

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-02T00:16:59', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'dde515a4-9731-425b-81fc-1928e2fc0173' User entered 'None (1)'	System	02 Oct 2020 06:17:07
	System	02 Oct 2020 06:17:07

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-02T00:17:04', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'dde515a4-9731-425b-81fc-1928e2fc0173' User entered '02 Oct 2020 00:17'	System	02 Oct 2020 06:17:07
	System	02 Oct 2020 06:17:07

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	28 Sep 2020 18:07:40
User entered 'Day 5'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-03T00:41:01', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '64b8cedd-9cfd-4ddd-9eec-3ddd337f32ae' User entered 'None (1)'	System	03 Oct 2020 06:41:15
	System	03 Oct 2020 06:41:15

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-03T00:41:05', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '64b8cedd-9cfd-4ddd-9eec-3ddd337f32ae' User entered 'No (N)'	System	03 Oct 2020 06:41:15
	System	03 Oct 2020 06:41:15

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-03T00:41:07', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '64b8cedd-9cfd-4ddd-9eec-3ddd337f32ae' User entered 'No (N)'	System	03 Oct 2020 06:41:15
	System	03 Oct 2020 06:41:15

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-03T00:41:11', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '64b8cedd-9cfd-4ddd-9eec-3ddd337f32ae'	System	03 Oct 2020 06:41:15
User entered 'None (1)'	System	03 Oct 2020 06:41:15

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-03T00:41:14', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '64b8cedd-9cfd-4ddd-9eec-3ddd337f32ae' User entered '03 Oct 2020 00:41'	System	03 Oct 2020 06:41:15
	System	03 Oct 2020 06:41:15

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	28 Sep 2020 18:07:40
User entered 'Day 6'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-03T22:22:50', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'c44f43d0-d83e-4280-a94b-8fcd2e566aea'	System	04 Oct 2020 04:23:30
User entered 'None (1)'	System	04 Oct 2020 04:23:30

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:18:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-03T22:22:53', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'c44f43d0-d83e-4280-a94b-8fcd2e566aea'	System	04 Oct 2020 04:23:30
User entered 'No (N)'	System	04 Oct 2020 04:23:30

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-03T22:22:57', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'c44f43d0-d83e-4280-a94b-8fcd2e566aea'	System	04 Oct 2020 04:23:30
User entered 'No (N)'	System	04 Oct 2020 04:23:30

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-03T22:23:15', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'c44f43d0-d83e-4280-a94b-8fcd2e566aea'	System	04 Oct 2020 04:23:30
User entered 'None (1)'	System	04 Oct 2020 04:23:30

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-03T22:23:25', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'c44f43d0-d83e-4280-a94b-8fcd2e566aea' User entered '03 Oct 2020 22:23'	System	04 Oct 2020 04:23:30
	System	04 Oct 2020 04:23:30

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	28 Sep 2020 18:07:40
User entered 'Day 7'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-04T20:29:55', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '68a6e0ea-95af-435a-90ca-d79474b2f26b' User entered 'None (1)'	System	05 Oct 2020 02:30:18
	System	05 Oct 2020 02:30:18

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:18:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-04T20:30:01', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '68a6e0ea-95af-435a-90ca-d79474b2f26b' User entered 'No (N)'	System	05 Oct 2020 02:30:18
	System	05 Oct 2020 02:30:18

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-04T20:30:04', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '68a6e0ea-95af-435a-90ca-d79474b2f26b' User entered 'No (N)'	System	05 Oct 2020 02:30:18
	System	05 Oct 2020 02:30:18

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-04T20:30:12', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '68a6e0ea-95af-435a-90ca-d79474b2f26b'	System	05 Oct 2020 02:30:18
User entered 'None (1)'	System	05 Oct 2020 02:30:18

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-04T20:30:16', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '68a6e0ea-95af-435a-90ca-d79474b2f26b' User entered '04 Oct 2020 20:30'	System	05 Oct 2020 02:30:18
	System	05 Oct 2020 02:30:18

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	28 Sep 2020 18:07:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-28T12:31:54', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '4fee513d-4463-49f9-853c-b971424da245'	System	28 Sep 2020 18:32:48
User entered 'None (0)'	System	28 Sep 2020 18:32:48

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-28T12:32:01', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '4fee513d-4463-49f9-853c-b971424da245'	System	28 Sep 2020 18:32:48
User entered 'None (0)'	System	28 Sep 2020 18:32:48

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-28T12:32:11', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '4fee513d-4463-49f9-853c-b971424da245'	System	28 Sep 2020 18:32:48
User entered 'None (0)'	System	28 Sep 2020 18:32:48

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-28T12:32:18', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '4fee513d-4463-49f9-853c-b971424da245' User entered 'None (0)'	System	28 Sep 2020 18:32:48
	System	28 Sep 2020 18:32:48

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-28T12:32:24', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '4fee513d-4463-49f9-853c-b971424da245'	System	28 Sep 2020 18:32:48
User entered 'None (0)'	System	28 Sep 2020 18:32:48

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-28T12:32:30', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '4fee513d-4463-49f9-853c-b971424da245'	System	28 Sep 2020 18:32:48
User entered 'None (0)'	System	28 Sep 2020 18:32:48

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-28T12:32:41', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '4fee513d-4463-49f9-853c-b971424da245'	System	28 Sep 2020 18:32:48
User entered 'No (N)'	System	28 Sep 2020 18:32:48

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-28T12:32:46', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '4fee513d-4463-49f9-853c-b971424da245' User entered '28 Sep 2020 12:32'	System	28 Sep 2020 18:32:48
	System	28 Sep 2020 18:32:48

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '28 Sep 2020 12:12'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '28 Sep 2020 14:42'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	28 Sep 2020 18:07:40
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-28T21:27:23', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '59ab4385-a99d-4134-b4fc-f64510c14dd7' User entered 'None (0)'	System	29 Sep 2020 03:28:00
	System	29 Sep 2020 03:28:00

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-28T21:27:31', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '59ab4385-a99d-4134-b4fc-f64510c14dd7' User entered 'None (0)'	System	29 Sep 2020 03:28:00
	System	29 Sep 2020 03:28:00

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-28T21:27:37', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '59ab4385-a99d-4134-b4fc-f64510c14dd7' User entered 'None (0)'	System	29 Sep 2020 03:28:00
	System	29 Sep 2020 03:28:00

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-28T21:27:43', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '59ab4385-a99d-4134-b4fc-f64510c14dd7' User entered 'None (0)'	System	29 Sep 2020 03:28:00
	System	29 Sep 2020 03:28:00

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-28T21:27:46', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '59ab4385-a99d-4134-b4fc-f64510c14dd7' User entered 'None (0)'	System	29 Sep 2020 03:28:00
	System	29 Sep 2020 03:28:00

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-28T21:27:49', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '59ab4385-a99d-4134-b4fc-f64510c14dd7' User entered 'None (0)'	System	29 Sep 2020 03:28:00
	System	29 Sep 2020 03:28:00

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-28T21:27:54', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '59ab4385-a99d-4134-b4fc-f64510c14dd7' User entered 'No (N)'	System	29 Sep 2020 03:28:00
	System	29 Sep 2020 03:28:00

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-28T21:27:57', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '59ab4385-a99d-4134-b4fc-f64510c14dd7' User entered '28 Sep 2020 21:27'	System	29 Sep 2020 03:28:00
	System	29 Sep 2020 03:28:00

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '28 Sep 2020 15:37'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	28 Sep 2020 18:07:40
User entered 'Day 2'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-29T20:05:57', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'bc7b0b91-0518-4e51-bac7-3a9a704f97f0'	System	30 Sep 2020 02:07:34
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	30 Sep 2020 02:07:34

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-29T20:06:09', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'bc7b0b91-0518-4e51-bac7-3a9a704f97f0'	System	30 Sep 2020 02:07:34
User entered 'Significant; prevents daily activity (3)'	System	30 Sep 2020 02:07:34

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-29T20:06:16', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'bc7b0b91-0518-4e51-bac7-3a9a704f97f0'	System	30 Sep 2020 02:07:34
User entered 'Significant; prevents daily activity (3)'	System	30 Sep 2020 02:07:34

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-29T20:06:29', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'bc7b0b91-0518-4e51-bac7-3a9a704f97f0' User entered 'Significant; prevents daily activity (3)'	System	30 Sep 2020 02:07:34
	System	30 Sep 2020 02:07:34

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-29T20:06:49', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'bc7b0b91-0518-4e51-bac7-3a9a704f97f0'	System	30 Sep 2020 02:07:34
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	30 Sep 2020 02:07:34

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-29T20:06:57', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'bc7b0b91-0518-4e51-bac7-3a9a704f97f0'	System	30 Sep 2020 02:07:34
User entered 'Some interference with activity not requiring medical attention (2)'	System	30 Sep 2020 02:07:34

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-29T20:07:07', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'bc7b0b91-0518-4e51-bac7-3a9a704f97f0' User entered 'Yes (Y)'	System	30 Sep 2020 02:07:34
	System	30 Sep 2020 02:07:34

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-09-29T20:07:31', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'bc7b0b91-0518-4e51-bac7-3a9a704f97f0' User entered '29 Sep 2020 20:07'	System	30 Sep 2020 02:07:34
	System	30 Sep 2020 02:07:34

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	28 Sep 2020 18:07:40
User entered 'Day 3'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-01T04:05:48', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '4a6a4dfd-28ac-4928-8dae-90553ba9afa1'	System	01 Oct 2020 10:06:50
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	01 Oct 2020 10:06:50

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-01T04:05:55', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '4a6a4dfd-28ac-4928-8dae-90553ba9afa1'	System	01 Oct 2020 10:06:50
User entered 'Significant; prevents daily activity (3)'	System	01 Oct 2020 10:06:50

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-01T04:06:08', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '4a6a4dfd-28ac-4928-8dae-90553ba9afa1'	System	01 Oct 2020 10:06:50
User entered 'Some interference with activity (2)'	System	01 Oct 2020 10:06:50

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-01T04:06:15', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '4a6a4dfd-28ac-4928-8dae-90553ba9afa1'	System	01 Oct 2020 10:06:50
User entered 'Some interference with activity (2)'	System	01 Oct 2020 10:06:50

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-01T04:06:25', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '4a6a4dfd-28ac-4928-8dae-90553ba9afa1'	System	01 Oct 2020 10:06:50
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	01 Oct 2020 10:06:50

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-01T04:06:34', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '4a6a4dfd-28ac-4928-8dae-90553ba9afa1'	System	01 Oct 2020 10:06:50
User entered 'No interference with activity (1)'	System	01 Oct 2020 10:06:50

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-01T04:06:42', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '4a6a4dfd-28ac-4928-8dae-90553ba9afa1' User entered 'No (N)'	System	01 Oct 2020 10:06:50
	System	01 Oct 2020 10:06:50

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-01T04:06:47', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '4a6a4dfd-28ac-4928-8dae-90553ba9afa1' User entered '01 Oct 2020 04:06'	System	01 Oct 2020 10:06:50
	System	01 Oct 2020 10:06:50

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	28 Sep 2020 18:07:40
User entered 'Day 4'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-02T00:17:14', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'a349e914-83a7-4af3-82ca-569605922bf1'	System	02 Oct 2020 06:18:27
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	02 Oct 2020 06:18:27

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-02T00:17:20', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'a349e914-83a7-4af3-82ca-569605922bf1' User entered 'Some interference with activity (2)'	System	02 Oct 2020 06:18:27
	System	02 Oct 2020 06:18:27

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-02T00:17:28', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'a349e914-83a7-4af3-82ca-569605922bf1' User entered 'Some interference with activity (2)'	System	02 Oct 2020 06:18:27
	System	02 Oct 2020 06:18:27

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-02T00:17:55', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'a349e914-83a7-4af3-82ca-569605922bf1' User entered 'Some interference with activity (2)'	System	02 Oct 2020 06:18:27
	System	02 Oct 2020 06:18:27

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-02T00:18:06', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'a349e914-83a7-4af3-82ca-569605922bf1'	System	02 Oct 2020 06:18:27
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	02 Oct 2020 06:18:27

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-02T00:18:13', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'a349e914-83a7-4af3-82ca-569605922bf1' User entered 'No interference with activity (1)'	System	02 Oct 2020 06:18:27
	System	02 Oct 2020 06:18:27

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-02T00:18:22', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'a349e914-83a7-4af3-82ca-569605922bf1' User entered 'No (N)'	System	02 Oct 2020 06:18:27
	System	02 Oct 2020 06:18:27

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-02T00:18:25', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'a349e914-83a7-4af3-82ca-569605922bf1' User entered '02 Oct 2020 00:18'	System	02 Oct 2020 06:18:27
	System	02 Oct 2020 06:18:27

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	28 Sep 2020 18:07:40
User entered 'Day 5'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-03T00:41:25', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '57ae367d-a2c7-4d60-8b46-0f0e7a283ffd'	System	03 Oct 2020 06:42:14
User entered 'No interference with activity (1)'	System	03 Oct 2020 06:42:14

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-03T00:41:29', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '57ae367d-a2c7-4d60-8b46-0f0e7a283ffd'	System	03 Oct 2020 06:42:14
User entered 'Some interference with activity (2)'	System	03 Oct 2020 06:42:14

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-03T00:41:32', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '57ae367d-a2c7-4d60-8b46-0f0e7a283ffd'	System	03 Oct 2020 06:42:14
User entered 'Some interference with activity (2)'	System	03 Oct 2020 06:42:14

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-03T00:41:35', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '57ae367d-a2c7-4d60-8b46-0f0e7a283ffd'	System	03 Oct 2020 06:42:14
User entered 'Some interference with activity (2)'	System	03 Oct 2020 06:42:14

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-03T00:41:42', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '57ae367d-a2c7-4d60-8b46-0f0e7a283ffd'	System	03 Oct 2020 06:42:14
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	03 Oct 2020 06:42:14

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-03T00:41:50', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '57ae367d-a2c7-4d60-8b46-0f0e7a283ffd'	System	03 Oct 2020 06:42:14
User entered 'No interference with activity (1)'	System	03 Oct 2020 06:42:14

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-03T00:42:09', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '57ae367d-a2c7-4d60-8b46-0f0e7a283ffd'	System	03 Oct 2020 06:42:14
User entered 'No (N)'	System	03 Oct 2020 06:42:14

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-03T00:42:13', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '57ae367d-a2c7-4d60-8b46-0f0e7a283ffd' User entered '03 Oct 2020 00:42'	System	03 Oct 2020 06:42:14
	System	03 Oct 2020 06:42:14

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	28 Sep 2020 18:07:40
User entered 'Day 6'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-03T22:23:33', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'e161ee31-f4b4-4f3a-b6c1-794c6e729088'	System	04 Oct 2020 04:24:24
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	04 Oct 2020 04:24:24

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-03T22:23:37', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'e161ee31-f4b4-4f3a-b6c1-794c6e729088'	System	04 Oct 2020 04:24:24
User entered 'Some interference with activity (2)'	System	04 Oct 2020 04:24:24

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-03T22:23:44', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'e161ee31-f4b4-4f3a-b6c1-794c6e729088'	System	04 Oct 2020 04:24:24
User entered 'Some interference with activity (2)'	System	04 Oct 2020 04:24:24

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-03T22:23:48', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'e161ee31-f4b4-4f3a-b6c1-794c6e729088'	System	04 Oct 2020 04:24:24
User entered 'Some interference with activity (2)'	System	04 Oct 2020 04:24:24

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-03T22:23:58', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'e161ee31-f4b4-4f3a-b6c1-794c6e729088'	System	04 Oct 2020 04:24:24
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	04 Oct 2020 04:24:24

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-03T22:24:03', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'e161ee31-f4b4-4f3a-b6c1-794c6e729088'	System	04 Oct 2020 04:24:24
User entered 'Some interference with activity not requiring medical attention (2)'	System	04 Oct 2020 04:24:24

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-03T22:24:19', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'e161ee31-f4b4-4f3a-b6c1-794c6e729088'	System	04 Oct 2020 04:24:24
User entered 'No (N)'	System	04 Oct 2020 04:24:24

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-03T22:24:22', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'e161ee31-f4b4-4f3a-b6c1-794c6e729088' User entered '03 Oct 2020 22:24'	System	04 Oct 2020 04:24:24
	System	04 Oct 2020 04:24:24

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	28 Sep 2020 18:07:40
User entered 'Day 7'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-04T20:30:26', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '88e458ed-4b35-4d02-af1f-77df99e53fe6'	System	05 Oct 2020 02:31:12
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	05 Oct 2020 02:31:12

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-04T20:30:31', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '88e458ed-4b35-4d02-af1f-77df99e53fe6'	System	05 Oct 2020 02:31:12
User entered 'Some interference with activity (2)'	System	05 Oct 2020 02:31:12

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-04T20:30:38', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '88e458ed-4b35-4d02-af1f-77df99e53fe6'	System	05 Oct 2020 02:31:12
User entered 'Some interference with activity (2)'	System	05 Oct 2020 02:31:12

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-04T20:30:42', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '88e458ed-4b35-4d02-af1f-77df99e53fe6'	System	05 Oct 2020 02:31:12
User entered 'Some interference with activity (2)'	System	05 Oct 2020 02:31:12

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-04T20:30:53', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '88e458ed-4b35-4d02-af1f-77df99e53fe6'	System	05 Oct 2020 02:31:12
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	05 Oct 2020 02:31:12

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-04T20:31:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '88e458ed-4b35-4d02-af1f-77df99e53fe6'	System	05 Oct 2020 02:31:12
User entered 'Some interference with activity not requiring medical attention (2)'	System	05 Oct 2020 02:31:12

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-04T20:31:06', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '88e458ed-4b35-4d02-af1f-77df99e53fe6' User entered 'No (N)'	System	05 Oct 2020 02:31:12
	System	05 Oct 2020 02:31:12

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-04T20:31:09', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '88e458ed-4b35-4d02-af1f-77df99e53fe6' User entered '04 Oct 2020 20:31'	System	05 Oct 2020 02:31:12
	System	05 Oct 2020 02:31:12

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 18:07:40

US3892032

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	04 Oct 2020 04:24:24
User entered 'Day 8'	System	04 Oct 2020 04:24:24

US3892032

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-05T23:55:26', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'b7d9dae8-d0c3-4a7a-8f9d-2851d2421b6a'	System	06 Oct 2020 05:55:35
User entered 'No interference with activity (1)'	System	06 Oct 2020 05:55:35

US3892032

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-05T23:55:31', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'b7d9dae8-d0c3-4a7a-8f9d-2851d2421b6a' User entered '05 Oct 2020 23:55'	System	06 Oct 2020 05:55:35
	System	06 Oct 2020 05:55:35

US3892032

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 04:24:24

US3892032

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 04:24:24

US3892032

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	05 Oct 2020 02:31:12
User entered 'Day 9'	System	05 Oct 2020 02:31:12

US3892032

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-06T23:31:35', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'a68cc8bd-f18d-463f-9b0d-0d632774b2f6'	System	07 Oct 2020 05:31:45
User entered 'No interference with activity (1)'	System	07 Oct 2020 05:31:45

US3892032

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-06T23:31:44', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'a68cc8bd-f18d-463f-9b0d-0d632774b2f6' User entered '06 Oct 2020 23:31'	System	07 Oct 2020 05:31:45
	System	07 Oct 2020 05:31:45

US3892032

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 02:31:12

US3892032

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 02:31:12

US3892032

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	06 Oct 2020 05:55:35
User entered 'Day 10'	System	06 Oct 2020 05:55:35

US3892032

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-08T00:22:07', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '8411dd71-48b3-43af-8e84-c7dd2d0e952d'	System	08 Oct 2020 06:22:14
User entered 'No interference with activity (1)'	System	08 Oct 2020 06:22:14

US3892032

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-08T00:22:11', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '8411dd71-48b3-43af-8e84-c7dd2d0e952d' User entered '08 Oct 2020 00:22'	System	08 Oct 2020 06:22:14
	System	08 Oct 2020 06:22:14

US3892032

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 05:55:35

US3892032

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 05:55:35

US3892032

Folder: Diary Dose 2 (1)

Form: Headache_Day(11)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	07 Oct 2020 05:31:45
User entered 'Day 11'	System	07 Oct 2020 05:31:45

US3892032

Folder: Diary Dose 2 (1)

Form: Headache_Day(11)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-09T10:25:03', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'd538e002-325a-415a-bfef-9bdcd2b4a8d7'	System	09 Oct 2020 16:25:11
User entered 'No interference with activity (1)'	System	09 Oct 2020 16:25:11

US3892032

Folder: Diary Dose 2 (1)

Form: Headache_Day(11)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-09T10:25:08', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'd538e002-325a-415a-bfef-9bdcd2b4a8d7'	System	09 Oct 2020 16:25:11
User entered '09 Oct 2020 10:25'	System	09 Oct 2020 16:25:11

US3892032

Folder: Diary Dose 2 (1)

Form: Headache_Day(11)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 05:31:45

US3892032

Folder: Diary Dose 2 (1)

Form: Headache_Day(11)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 05:31:45

US3892032

Folder: Diary Dose 2 (1)

Form: Headache_Day(12)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	08 Oct 2020 06:22:14
User entered 'Day 12'	System	08 Oct 2020 06:22:14

US3892032

Folder: Diary Dose 2 (1)

Form: Headache_Day(12)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-09T20:47:55', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '6302111c-6957-42d0-b111-0eab9e6ad2b8'	System	10 Oct 2020 02:48:00
User entered 'No interference with activity (1)'	System	10 Oct 2020 02:48:00

US3892032

Folder: Diary Dose 2 (1)

Form: Headache_Day(12)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-09T20:47:59', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '6302111c-6957-42d0-b111-0eab9e6ad2b8' User entered '09 Oct 2020 20:47'	System	10 Oct 2020 02:48:00
	System	10 Oct 2020 02:48:00

US3892032

Folder: Diary Dose 2 (1)

Form: Headache_Day(12)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 06:22:14

US3892032

Folder: Diary Dose 2 (1)

Form: Headache_Day(12)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 06:22:14

US3892032

Folder: Diary Dose 2 (1)

Form: Headache_Day(13)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	09 Oct 2020 16:25:11
User entered 'Day 13'	System	09 Oct 2020 16:25:11

US3892032

Folder: Diary Dose 2 (1)

Form: Headache_Day(13)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-10T23:39:22', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'bfd013af-5564-45d7-8bdc-738a484977c3' User entered 'None (0)'	System	11 Oct 2020 05:39:28
	System	11 Oct 2020 05:39:28

US3892032

Folder: Diary Dose 2 (1)

Form: Headache_Day(13)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-10T23:39:26', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'bfd013af-5564-45d7-8bdc-738a484977c3' User entered '10 Oct 2020 23:39'	System	11 Oct 2020 05:39:28
	System	11 Oct 2020 05:39:28

US3892032

Folder: Diary Dose 2 (1)

Form: Headache_Day(13)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 16:25:11

US3892032

Folder: Diary Dose 2 (1)

Form: Headache_Day(13)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 16:25:11

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	04 Oct 2020 04:24:24
User entered 'Day 8'	System	04 Oct 2020 04:24:24

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-05T23:55:37', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '101c4ebf-add8-4e4d-bf81-862dc0f7a275'	System	06 Oct 2020 05:55:47
User entered 'Some interference with activity (2)'	System	06 Oct 2020 05:55:47

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-05T23:55:44', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '101c4ebf-add8-4e4d-bf81-862dc0f7a275'	System	06 Oct 2020 05:55:47
User entered '05 Oct 2020 23:55'	System	06 Oct 2020 05:55:47

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 04:24:24

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 04:24:24

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	05 Oct 2020 02:31:12
User entered 'Day 9'	System	05 Oct 2020 02:31:12

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-06T23:31:51', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '0a93662d-ca09-4934-a5c3-507ac57d7184' User entered 'Significant; prevents daily activity (3)'	System	07 Oct 2020 05:31:59
	System	07 Oct 2020 05:31:59

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-06T23:31:58', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '0a93662d-ca09-4934-a5c3-507ac57d7184' User entered '06 Oct 2020 23:31'	System	07 Oct 2020 05:31:59
	System	07 Oct 2020 05:31:59

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 02:31:12

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 02:31:12

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	06 Oct 2020 05:55:47
User entered 'Day 10'	System	06 Oct 2020 05:55:47

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-08T00:22:21', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'dcdd088c-2634-4170-92e3-0644da58ec2b'	System	08 Oct 2020 06:22:30
User entered 'Some interference with activity (2)'	System	08 Oct 2020 06:22:30

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-08T00:22:26', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'dcdd088c-2634-4170-92e3-0644da58ec2b' User entered '08 Oct 2020 00:22'	System	08 Oct 2020 06:22:30
	System	08 Oct 2020 06:22:30

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 05:55:47

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 05:55:47

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	07 Oct 2020 05:31:59
User entered 'Day 11'	System	07 Oct 2020 05:31:59

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-09T10:25:17', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '13b7b012-8632-45cc-8eb7-d915e7e6c1fb' User entered 'Significant; prevents daily activity (3)'	System	09 Oct 2020 16:25:40
	System	09 Oct 2020 16:25:40

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-09T10:25:35', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '13b7b012-8632-45cc-8eb7-d915e7e6c1fb' User entered '09 Oct 2020 10:25'	System	09 Oct 2020 16:25:40
	System	09 Oct 2020 16:25:40

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 05:31:59

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 05:31:59

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	08 Oct 2020 06:22:30
User entered 'Day 12'	System	08 Oct 2020 06:22:30

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-09T20:48:04', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '9f70333e-230a-45b6-9af8-c1f51c5021b1'	System	10 Oct 2020 02:48:10
User entered 'Some interference with activity (2)'	System	10 Oct 2020 02:48:10

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-09T20:48:09', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '9f70333e-230a-45b6-9af8-c1f51c5021b1' User entered '09 Oct 2020 20:48'	System	10 Oct 2020 02:48:10
	System	10 Oct 2020 02:48:10

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 06:22:30

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 06:22:30

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	09 Oct 2020 16:25:40
User entered 'Day 13'	System	09 Oct 2020 16:25:40

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-10T23:39:37', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '1569e364-3213-42af-a7b7-b052132874a1'	System	11 Oct 2020 05:39:43
User entered 'Some interference with activity (2)'	System	11 Oct 2020 05:39:43

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-10T23:39:40', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '1569e364-3213-42af-a7b7-b052132874a1' User entered '10 Oct 2020 23:39'	System	11 Oct 2020 05:39:43
	System	11 Oct 2020 05:39:43

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 16:25:40

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 16:25:40

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	10 Oct 2020 02:48:10
User entered 'Day 14'	System	10 Oct 2020 02:48:10

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '11 Oct 2020 12:00'	System	10 Oct 2020 02:48:10

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '12 Oct 2020 11:59'	System	10 Oct 2020 02:48:10

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	11 Oct 2020 05:39:43
User entered 'Day 15'	System	11 Oct 2020 05:39:43

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 10:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '12 Oct 2020 12:00'	System	11 Oct 2020 05:39:43

US3892032

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '13 Oct 2020 11:59'	System	11 Oct 2020 05:39:43

US3892032

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	04 Oct 2020 04:24:24
User entered 'Day 8'	System	04 Oct 2020 04:24:24

US3892032

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 10:18:29

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-05T23:55:54', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '849a2440-6090-4cbf-bb5c-b2aa53418b6c' User entered 'Significant; prevents daily activity (3)'	System	06 Oct 2020 05:56:03

US3892032

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-05T23:55:59', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '849a2440-6090-4cbf-bb5c-b2aa53418b6c' User entered '05 Oct 2020 23:55'	System	06 Oct 2020 05:56:03
	System	06 Oct 2020 05:56:03

US3892032

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 04:24:24

US3892032

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 04:24:24

US3892032

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	05 Oct 2020 02:31:12
User entered 'Day 9'	System	05 Oct 2020 02:31:12

US3892032

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 10:18:29

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-06T23:32:03', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'b0bd0a46-c5d0-4c43-a44f-9019f534e171'	System	07 Oct 2020 05:32:14
User entered 'Some interference with activity (2)'	System	07 Oct 2020 05:32:14

US3892032

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-06T23:32:12', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'b0bd0a46-c5d0-4c43-a44f-9019f534e171' User entered '06 Oct 2020 23:32'	System	07 Oct 2020 05:32:14
	System	07 Oct 2020 05:32:14

US3892032

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 02:31:12

US3892032

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 02:31:12

US3892032

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	06 Oct 2020 05:56:03
User entered 'Day 10'	System	06 Oct 2020 05:56:03

US3892032

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 10:18:29

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-08T00:22:33', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '0eea11de-5052-489b-b9ac-d4e9b65fe2fe'	System	08 Oct 2020 06:22:38
User entered 'Some interference with activity (2)'	System	08 Oct 2020 06:22:38

US3892032

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-08T00:22:37', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '0eea11de-5052-489b-b9ac-d4e9b65fe2fe' User entered '08 Oct 2020 00:22'	System	08 Oct 2020 06:22:38
	System	08 Oct 2020 06:22:38

US3892032

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 05:56:03

US3892032

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 05:56:03

US3892032

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	07 Oct 2020 05:32:14
User entered 'Day 11'	System	07 Oct 2020 05:32:14

US3892032

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 10 Jun 2021 10:18:29

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-09T10:25:44', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '275679bf-2dbb-4c6d-850e-03266e7bcad4'	System	09 Oct 2020 16:25:55
User entered 'Some interference with activity (2)'	System	09 Oct 2020 16:25:55

US3892032

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-09T10:25:50', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '275679bf-2dbb-4c6d-850e-03266e7bcad4' User entered '09 Oct 2020 10:25'	System	09 Oct 2020 16:25:55
	System	09 Oct 2020 16:25:55

US3892032

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 05:32:14

US3892032

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 05:32:14

US3892032

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	08 Oct 2020 06:22:38
User entered 'Day 12'	System	08 Oct 2020 06:22:38

US3892032

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 10 Jun 2021 10:18:29

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-09T20:48:22', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '877e917c-99f9-4b8b-a593-ef5916267fdc'	System	10 Oct 2020 02:48:27
User entered 'No interference with activity (1)'	System	10 Oct 2020 02:48:27

US3892032

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-09T20:48:25', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '877e917c-99f9-4b8b-a593-ef5916267fdc' User entered '09 Oct 2020 20:48'	System	10 Oct 2020 02:48:27
	System	10 Oct 2020 02:48:27

US3892032

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 06:22:38

US3892032

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 06:22:38

US3892032

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	09 Oct 2020 16:25:55
User entered 'Day 13'	System	09 Oct 2020 16:25:55

US3892032

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 10 Jun 2021 10:18:29

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-10T23:39:45', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '695b6000-ccdd-41fb-825f-c4e1afc7ba3f' User entered 'None (0)'	System	11 Oct 2020 05:39:53
	System	11 Oct 2020 05:39:53

US3892032

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-10T23:39:49', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '695b6000-ccdd-41fb-825f-c4e1afc7ba3f' User entered '10 Oct 2020 23:39'	System	11 Oct 2020 05:39:53
	System	11 Oct 2020 05:39:53

US3892032

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 16:25:55

US3892032

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 16:25:55

US3892032

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	04 Oct 2020 04:24:24
User entered 'Day 8'	System	04 Oct 2020 04:24:24

US3892032

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 10:18:29

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-05T23:56:05', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'a0fc86c8-6367-417d-85e5-526481b95bd2'	System	06 Oct 2020 05:56:11
User entered 'Some interference with activity (2)'	System	06 Oct 2020 05:56:11

US3892032

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-05T23:56:09', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'a0fc86c8-6367-417d-85e5-526481b95bd2' User entered '05 Oct 2020 23:56'	System	06 Oct 2020 05:56:11
	System	06 Oct 2020 05:56:11

US3892032

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 04:24:24

US3892032

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 04:24:24

US3892032

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	05 Oct 2020 02:31:12
User entered 'Day 9'	System	05 Oct 2020 02:31:12

US3892032

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 10:18:29

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-06T23:32:31', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'ef70da3c-53b3-41e8-a555-986e388957b3'	System	07 Oct 2020 05:32:49
User entered 'Some interference with activity (2)'	System	07 Oct 2020 05:32:49

US3892032

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-06T23:32:48', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'ef70da3c-53b3-41e8-a555-986e388957b3' User entered '06 Oct 2020 23:32'	System	07 Oct 2020 05:32:49
	System	07 Oct 2020 05:32:49

US3892032

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 02:31:12

US3892032

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 02:31:12

US3892032

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	06 Oct 2020 05:56:11
User entered 'Day 10'	System	06 Oct 2020 05:56:11

US3892032

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 10:18:29

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-08T00:22:58', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '2b491480-f79a-4149-a5f4-9a2c4c080c9d' User entered 'Some interference with activity (2)'	System	08 Oct 2020 06:23:05
	System	08 Oct 2020 06:23:05

US3892032

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-08T00:23:02', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '2b491480-f79a-4149-a5f4-9a2c4c080c9d' User entered '08 Oct 2020 00:23'	System	08 Oct 2020 06:23:05
	System	08 Oct 2020 06:23:05

US3892032

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 05:56:11

US3892032

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 05:56:11

US3892032

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	07 Oct 2020 05:32:49
User entered 'Day 11'	System	07 Oct 2020 05:32:49

US3892032

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 10:18:29

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-09T10:26:07', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '852f638d-a3dc-458c-80ca-b67a269f741e'	System	09 Oct 2020 16:26:13
User entered 'Some interference with activity (2)'	System	09 Oct 2020 16:26:13

US3892032

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-09T10:26:11', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '852f638d-a3dc-458c-80ca-b67a269f741e' User entered '09 Oct 2020 10:26'	System	09 Oct 2020 16:26:13
	System	09 Oct 2020 16:26:13

US3892032

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 05:32:49

US3892032

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 05:32:49

US3892032

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	08 Oct 2020 06:23:05
User entered 'Day 12'	System	08 Oct 2020 06:23:05

US3892032

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 10 Jun 2021 10:18:29

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-09T20:48:32', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'c7ad12ae-7c97-4e2c-a365-6e3d07b1dee3'	System	10 Oct 2020 02:48:38
User entered 'No interference with activity (1)'	System	10 Oct 2020 02:48:38

US3892032

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-09T20:48:35', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'c7ad12ae-7c97-4e2c-a365-6e3d07b1dee3' User entered '09 Oct 2020 20:48'	System	10 Oct 2020 02:48:38
	System	10 Oct 2020 02:48:38

US3892032

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 06:23:05

US3892032

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 06:23:05

US3892032

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	09 Oct 2020 16:26:13
User entered 'Day 13'	System	09 Oct 2020 16:26:13

US3892032

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 10 Jun 2021 10:18:29

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-10T23:39:59', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '3c9154c6-8f58-4cab-a0c9-c209a30a59d1' User entered 'None (0)'	System	11 Oct 2020 05:40:06
	System	11 Oct 2020 05:40:06

US3892032

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-10T23:40:02', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '3c9154c6-8f58-4cab-a0c9-c209a30a59d1' User entered '10 Oct 2020 23:40'	System	11 Oct 2020 05:40:06
	System	11 Oct 2020 05:40:06

US3892032

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 16:26:13

US3892032

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 16:26:13

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	04 Oct 2020 04:24:24
User entered 'Day 8'	System	04 Oct 2020 04:24:24

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 10:18:29

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-05T23:56:20', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'af48a7a7-ae2e-49e0-8f43-252df796b3c2'	System	06 Oct 2020 05:56:29
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	06 Oct 2020 05:56:29

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-05T23:56:26', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'af48a7a7-ae2e-49e0-8f43-252df796b3c2' User entered '05 Oct 2020 23:56'	System	06 Oct 2020 05:56:29
	System	06 Oct 2020 05:56:29

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 04:24:24

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 04:24:24

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(9)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	05 Oct 2020 02:31:12
User entered 'Day 9'	System	05 Oct 2020 02:31:12

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(9)

Generated On: 10 Jun 2021 10:18:29

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-06T23:33:07', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '5cc467aa-1b5c-4fd9-8a27-cabed9deebc7'	System	07 Oct 2020 05:33:26
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	07 Oct 2020 05:33:26

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(9)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-06T23:33:24', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '5cc467aa-1b5c-4fd9-8a27-cabcd9deebc7' User entered '06 Oct 2020 23:33'	System	07 Oct 2020 05:33:26
	System	07 Oct 2020 05:33:26

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(9)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 02:31:12

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(9)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 02:31:12

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(10)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	06 Oct 2020 05:56:29
User entered 'Day 10'	System	06 Oct 2020 05:56:29

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(10)

Generated On: 10 Jun 2021 10:18:29

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-08T00:22:47', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'da1fe823-4fc1-46bf-99e1-77bebdee8a34'	System	08 Oct 2020 06:22:54
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	08 Oct 2020 06:22:54

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(10)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-08T00:22:52', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'da1fe823-4fc1-46bf-99e1-77bebdee8a34' User entered '08 Oct 2020 00:22'	System	08 Oct 2020 06:22:54
	System	08 Oct 2020 06:22:54

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(10)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 05:56:29

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(10)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 05:56:29

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(11)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	07 Oct 2020 05:33:26
User entered 'Day 11'	System	07 Oct 2020 05:33:26

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(11)

Generated On: 10 Jun 2021 10:18:29

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-09T10:26:32', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'ac1a0716-dbd4-4639-8852-c0511e0f414a'	System	09 Oct 2020 16:26:39
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	09 Oct 2020 16:26:39

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(11)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-09T10:26:36', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'ac1a0716-dbd4-4639-8852-c0511e0f414a' User entered '09 Oct 2020 10:26'	System	09 Oct 2020 16:26:39
	System	09 Oct 2020 16:26:39

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(11)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 05:33:26

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(11)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 05:33:26

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(12)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	08 Oct 2020 06:22:54
User entered 'Day 12'	System	08 Oct 2020 06:22:54

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(12)

Generated On: 10 Jun 2021 10:18:29

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-09T20:48:41', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '54c7742a-d7c2-4454-a218-fdad17596c79'	System	10 Oct 2020 02:48:51
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	10 Oct 2020 02:48:51

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(12)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-09T20:48:50', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '54c7742a-d7c2-4454-a218-fdad17596c79' User entered '09 Oct 2020 20:48'	System	10 Oct 2020 02:48:51
	System	10 Oct 2020 02:48:51

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(12)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 06:22:54

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(12)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 06:22:54

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(13)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	09 Oct 2020 16:26:39
User entered 'Day 13'	System	09 Oct 2020 16:26:39

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(13)

Generated On: 10 Jun 2021 10:18:29

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-10T23:40:11', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'bb777f9e-1ac5-4354-9453-4053284b3904'	System	11 Oct 2020 05:40:16
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	11 Oct 2020 05:40:16

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(13)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-10T23:40:14', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'bb777f9e-1ac5-4354-9453-4053284b3904' User entered '10 Oct 2020 23:40'	System	11 Oct 2020 05:40:16
	System	11 Oct 2020 05:40:16

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(13)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 16:26:39

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(13)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 16:26:39

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(14)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	10 Oct 2020 02:48:51
User entered 'Day 14'	System	10 Oct 2020 02:48:51

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(14)

Generated On: 10 Jun 2021 10:18:29

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(14)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(14)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '11 Oct 2020 12:00'	System	10 Oct 2020 02:48:51

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(14)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '12 Oct 2020 11:59'	System	10 Oct 2020 02:48:51

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(15)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	11 Oct 2020 05:40:16
User entered 'Day 15'	System	11 Oct 2020 05:40:16

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(15)

Generated On: 10 Jun 2021 10:18:29

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(15)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(15)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '12 Oct 2020 12:00'	System	11 Oct 2020 05:40:16

US3892032

Folder: Diary Dose 2 (1)

Form: Nausea_Day(15)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '13 Oct 2020 11:59'	System	11 Oct 2020 05:40:16

US3892032

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	04 Oct 2020 04:24:24
User entered 'Day 8'	System	04 Oct 2020 04:24:24

US3892032

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 10:18:29

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-05T23:56:35', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '82cd7813-82a0-4659-bf7b-4537adf418da'	System	06 Oct 2020 05:56:40
User entered 'Some interference with activity not requiring medical attention (2)'	System	06 Oct 2020 05:56:40

US3892032

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 04:24:24

US3892032

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 04:24:24

US3892032

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-05T23:56:38', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '82cd7813-82a0-4659-bf7b-4537adf418da' User entered '05 Oct 2020 23:56'	System	06 Oct 2020 05:56:40
	System	06 Oct 2020 05:56:40

US3892032

Folder: Diary Dose 2 (1)

Form: Chills_Day(9)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	05 Oct 2020 02:31:12
User entered 'Day 9'	System	05 Oct 2020 02:31:12

US3892032

Folder: Diary Dose 2 (1)

Form: Chills_Day(9)

Generated On: 10 Jun 2021 10:18:29

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-06T23:33:41', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7983987a-c8e8-4938-848f-fc9ce7ebafba'	System	07 Oct 2020 05:33:56
User entered 'Some interference with activity not requiring medical attention (2)'	System	07 Oct 2020 05:33:56

US3892032

Folder: Diary Dose 2 (1)

Form: Chills_Day(9)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 02:31:12

US3892032

Folder: Diary Dose 2 (1)

Form: Chills_Day(9)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 02:31:12

US3892032

Folder: Diary Dose 2 (1)

Form: Chills_Day(9)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-06T23:33:54', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7983987a-c8e8-4938-848f-fc9ce7ebafba' User entered '06 Oct 2020 23:33'	System	07 Oct 2020 05:33:56
	System	07 Oct 2020 05:33:56

US3892032

Folder: Diary Dose 2 (1)

Form: Chills_Day(10)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	06 Oct 2020 05:56:40
User entered 'Day 10'	System	06 Oct 2020 05:56:40

US3892032

Folder: Diary Dose 2 (1)

Form: Chills_Day(10)

Generated On: 10 Jun 2021 10:18:29

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-08T00:23:09', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '355c5a3d-c214-44d3-b779-6483d6fdce03' User entered 'None (0)'	System	08 Oct 2020 06:23:16
	System	08 Oct 2020 06:23:16

US3892032

Folder: Diary Dose 2 (1)

Form: Chills_Day(10)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 05:56:40

US3892032

Folder: Diary Dose 2 (1)

Form: Chills_Day(10)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 05:56:40

US3892032

Folder: Diary Dose 2 (1)

Form: Chills_Day(10)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-08T00:23:13', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '355c5a3d-c214-44d3-b779-6483d6fdce03' User entered '08 Oct 2020 00:23'	System	08 Oct 2020 06:23:16
	System	08 Oct 2020 06:23:16

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	04 Oct 2020 04:22:47
User entered 'Day 8'	System	04 Oct 2020 04:22:47

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-05T23:56:46', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'ba541bfb-4d74-4054-a02d-6ea25ff6b991' User entered 'No (N)'	System	06 Oct 2020 05:56:57
	System	06 Oct 2020 05:56:57

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-05T23:56:52', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'ba541bfb-4d74-4054-a02d-6ea25ff6b991'	System	06 Oct 2020 05:56:57
User entered '05 Oct 2020 23:56'	System	06 Oct 2020 05:56:57

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 04:22:47

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 04:22:47

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	05 Oct 2020 02:29:53
User entered 'Day 9'	System	05 Oct 2020 02:29:53

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-06T23:34:01', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '217b22f0-caae-4eb1-ac8a-b361837522a8' User entered 'No (N)'	System	07 Oct 2020 05:34:11
	System	07 Oct 2020 05:34:11

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-06T23:34:08', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '217b22f0-caae-4eb1-ac8a-b361837522a8' User entered '06 Oct 2020 23:34'	System	07 Oct 2020 05:34:11
	System	07 Oct 2020 05:34:11

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 02:29:53

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 02:29:53

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	06 Oct 2020 05:55:15
User entered 'Day 10'	System	06 Oct 2020 05:55:15

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-08T00:23:19', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '94f0d857-8630-493e-8235-9597c32fec05'	System	08 Oct 2020 06:23:27
User entered 'Yes (Y)'	System	08 Oct 2020 06:23:27

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-08T00:23:23', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '94f0d857-8630-493e-8235-9597c32fec05' User entered '08 Oct 2020 00:23'	System	08 Oct 2020 06:23:27
	System	08 Oct 2020 06:23:27

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 05:55:15

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 05:55:15

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	07 Oct 2020 05:31:31
User entered 'Day 11'	System	07 Oct 2020 05:31:31

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-09T10:26:41', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '764a373d-0429-42f0-b7fb-143e7fb41d19'	System	09 Oct 2020 16:26:58
User entered 'No (N)'	System	09 Oct 2020 16:26:58

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-09T10:26:55', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '764a373d-0429-42f0-b7fb-143e7fb41d19'	System	09 Oct 2020 16:26:58
User entered '09 Oct 2020 10:26'	System	09 Oct 2020 16:26:58

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 05:31:31

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 05:31:31

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	08 Oct 2020 06:22:14
User entered 'Day 12'	System	08 Oct 2020 06:22:14

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-09T20:48:54', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'd25b5ebe-f2b0-446e-80fe-51459e76f0a1' User entered 'No (N)'	System	10 Oct 2020 02:49:00
	System	10 Oct 2020 02:49:00

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-09T20:48:58', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'd25b5ebe-f2b0-446e-80fe-51459e76f0a1' User entered '09 Oct 2020 20:48'	System	10 Oct 2020 02:49:00
	System	10 Oct 2020 02:49:00

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 06:22:14

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 06:22:14

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	09 Oct 2020 16:25:11
User entered 'Day 13'	System	09 Oct 2020 16:25:11

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-10T23:40:19', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'bd95c7f5-f746-496a-85c9-fd50031b1da2'	System	11 Oct 2020 05:40:26
User entered 'No (N)'	System	11 Oct 2020 05:40:26

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-10-10T23:40:22', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'bd95c7f5-f746-496a-85c9-fd50031b1da2'	System	11 Oct 2020 05:40:26
User entered '10 Oct 2020 23:40'	System	11 Oct 2020 05:40:26

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 16:25:11

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 16:25:11

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	10 Oct 2020 02:48:00
User entered 'Day 14'	System	10 Oct 2020 02:48:00

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '11 Oct 2020 12:00'	System	10 Oct 2020 02:48:00

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '12 Oct 2020 11:59'	System	10 Oct 2020 02:48:00

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	11 Oct 2020 05:39:43
User entered 'Day 15'	System	11 Oct 2020 05:39:43

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 10:18:29

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 08:21:49

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 10:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 10:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '12 Oct 2020 12:00'	System	11 Oct 2020 05:39:43

US3892032

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 10:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
User entered '13 Oct 2020 11:59'	System	11 Oct 2020 05:39:43

US3892032

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 20:04:00
User closed query 'Since subject is in illness visits, this should be noted as NO, as these visits are not to be performed, since subject is getting daily phone calls. Kindly refer to CCG V2 for details on data entry. Thank you.' (Site from CRA).	(b) (4), (b) (6)	08 Dec 2020 20:03:57
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	02 Dec 2020 15:34:04
User entered 'No (N)' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	02 Dec 2020 15:34:04
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	02 Dec 2020 15:33:28
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	02 Dec 2020 15:33:28
User entered 'Yes (Y)' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	02 Dec 2020 15:33:28
Comment added 'Subject was in Convalescent period, Safety call was skipped.'	Andryelle Toledo (b) (4) (b) (4)	02 Dec 2020 15:32:59
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Dec 2020 15:32:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Dec 2020 15:32:52
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	02 Dec 2020 15:32:52
User entered 'No (N)' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	02 Dec 2020 15:32:52

US3892032

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Dec 2020 15:32:07
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	02 Dec 2020 15:32:07
User entered empty; reason for change Data Entry Error	Andryelle Toledo (b) (4)	02 Dec 2020 15:32:07
Comment added 'Per CRA clarification. Subject was performing Telemedicine (Convalescent Periodo - Illness visit). CRA requested data to be disregard.'	Andryelle Toledo (b) (4)	19 Nov 2020 23:41:03
Query 'Since subject is in illness visits, this should be noted as NO, as these visits are not to be performed, since subject is getting daily phone calls. Kindly refer to CCG V2 for details on data entry. Thank you.'	Leslie Iverson (b) (4)	18 Nov 2020 17:30:08
answered with 'Changed to No, since contact was during convalescent period.' (Site from CRA).	(b) (4)	
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	18 Nov 2020 17:29:11
User entered 'No (N)' reason for change: Data Entry Error	Leslie Iverson (b) (4)	18 Nov 2020 17:29:11
User opened query 'Since subject is in illness visits, this should be noted as NO, as these visits are not to be performed, since subject is getting daily phone calls. Kindly refer to CCG V2 for details on data entry. Thank you.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 19:40:14
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 21:56:15
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:53:42
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:48:19
	(b) (4)	

US3892032

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 20:04:00
User entered empty; reason for change Data Entry Error	Leslie Iverson (b) (4)	18 Nov 2020 17:29:11
DataPoint Un-verified.	(b) (4)	27 Oct 2020 21:56:18
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:53:42
User entered '05 Oct 2020'	Andryelle Toledo (b) (4)	21 Oct 2020 14:48:19
	(b) (4)	

US3892032

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 20:04:00
User entered empty; reason for change Data Entry Error	Andryelle Toledo (b) (4)	02 Dec 2020 15:34:04
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	Leslie Iverson (b) (4)	18 Nov 2020 17:30:19
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:56:19
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:53:42
User entered 'Contact Made (CONTACT MADE)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:48:19

US3892032

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 20:04:00
User entered empty; reason for change Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	02 Dec 2020 15:34:04
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	18 Nov 2020 17:30:50
User entered 'Subject was contacted for convalescent period and not safety call.' reason for change: Data Entry Error	Leslie Iverson (b) (4) (b) (4)	18 Nov 2020 17:30:50
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	18 Nov 2020 17:30:19
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 21:56:23
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:53:42
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:48:19

US3892032

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:53:53
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:48:30

US3892032

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered 'I'	System	21 Oct 2020 14:48:30

US3892032

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:38:57
Query 'If subject is in illness visit (telemedicine portion of protocol), this data is captured. Kindly remove data accordingly. Thank you' canceled (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 19:37:15
User opened query 'If subject is in illness visit (telemedicine portion of protocol), this data is captured. Kindly remove data accordingly. Thank you' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 19:33:37
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 15:04:05

US3892032

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:38:57
User entered '12 Oct 2020'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 15:04:05

US3892032

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:38:57
User entered 'Contact Made (CONTACT MADE)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 15:04:05

US3892032

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:38:57
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 15:04:05

US3892032

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:39:12
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 15:04:11

US3892032

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered 'I'	System	21 Oct 2020 15:04:11

US3892032

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:40:54
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 15:04:24

US3892032

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:40:54
User entered '19 Oct 2020'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 15:04:24

US3892032

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:40:54
User entered 'Contact Made (CONTACT MADE)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 15:04:24

US3892032

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:40:54
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 15:04:24

US3892032

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:40:17
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 15:04:30

US3892032

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered 'I'	System	21 Oct 2020 15:04:30

US3892032

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:41:33
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	27 Oct 2020 19:40:27

US3892032

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:41:33
User entered '27 Oct 2020'	Andryelle Toledo (b) (4)	27 Oct 2020 19:40:27

US3892032

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:41:33
User entered 'Clinic (Clinic)'	Andryelle Toledo (b) (4) (b) (4)	27 Oct 2020 19:40:27

US3892032

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered 'VISIT3'	System	27 Oct 2020 19:40:27

US3892032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:44:38
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	27 Oct 2020 19:41:08

US3892032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:44:38
User entered '27 Oct 2020'	Andryelle Toledo (b) (4) (b) (4)	27 Oct 2020 19:41:08

US3892032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:44:38
User entered '10:25'	Andryelle Toledo (b) (4) (b) (4)	27 Oct 2020 19:41:08

US3892032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered '27 Oct 2020 10:25'	System	27 Oct 2020 19:41:08

US3892032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:44:38
User entered '97.2' F	Andryelle Toledo (b) (4) (b) (4)	27 Oct 2020 19:41:08

US3892032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:44:38
User entered 'Oral (Oral)'	Andryelle Toledo (b) (4) (b) (4)	27 Oct 2020 19:41:08

US3892032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:44:38
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	27 Oct 2020 19:41:08

US3892032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:44:38
User entered '98'	Andryelle Toledo (b) (4) (b) (4)	27 Oct 2020 19:41:08

US3892032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered 'bpm'	System	27 Oct 2020 19:41:08

US3892032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:44:38
User entered '14'	Andryelle Toledo (b) (4) (b) (4)	27 Oct 2020 19:41:08

US3892032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered 'breaths/min'	System	27 Oct 2020 19:41:08

US3892032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
User closed query 'Per CDM: Per CCG V2.0 page 53, SBP \leq 89 or \geq 141 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 01:20:01
Query 'Per CDM: Per CCG V2.0 page 53, SBP \leq 89 or \geq 141 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' answered with 'Per PI: NCS' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 23:21:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:44:38
User opened query 'Per CDM: Per CCG V2.0 page 53, SBP \leq 89 or \geq 141 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 07:09:32
User entered '147'	Andryelle Toledo (b) (4) (b) (4)	27 Oct 2020 19:41:08

US3892032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered 'mmHg'	System	27 Oct 2020 19:41:08

US3892032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
User closed query 'Per CDM: Per CCG V2.0 page 53, Diastolic Blood Pressure \geq 91 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 01:20:03
Query 'Per CDM: Per CCG V2.0 page 53, Diastolic Blood Pressure \geq 91 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' answered with 'Per PI: NCS' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 23:21:59
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:44:38
User opened query 'Per CDM: Per CCG V2.0 page 53, Diastolic Blood Pressure \geq 91 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 07:09:43
User entered '92'	Andryelle Toledo (b) (4) (b) (4)	27 Oct 2020 19:41:08

US3892032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered 'mmHg'	System	27 Oct 2020 19:41:08

US3892032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03

US3892032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03

US3892032

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:18:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:44:19
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	27 Oct 2020 19:41:29

US3892032

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:18:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:44:19
User entered '27 Oct 2020'	Andryelle Toledo (b) (4) (b) (4)	27 Oct 2020 19:41:29

US3892032

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
User closed query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 3 Day 57 with a Collection Date of 27OCT2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 12:19:37
Query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 3 Day 57 with a Collection Date of 27OCT2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate. ' answered with 'Visit was performed, samples collected and confirmation from the Lab is attached to the chart.' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	02 Dec 2020 23:49:57
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:42:57
User opened query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 3 Day 57 with a Collection Date of 27OCT2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 19:07:13
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	27 Oct 2020 19:42:00

US3892032

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:42:57
User entered '27 Oct 2020'	Andryelle Toledo (b) (4) (b) (4)	27 Oct 2020 19:42:00

US3892032

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:42:57
User entered '10:56'	Andryelle Toledo (b) (4) (b) (4)	27 Oct 2020 19:42:00

US3892032

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered '27 Oct 2020 10:56'	System	27 Oct 2020 19:42:00

US3892032

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:41:39
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	27 Oct 2020 19:42:05

US3892032

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered 'I'	System	27 Oct 2020 19:42:05

US3892032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	31 Aug 2020 18:17:16
User entered 'Day 64'	System	31 Aug 2020 18:17:16

US3892032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-11-02T12:49:47', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'c43c72db-5e20-412f-91ed-7eb7b5f5607d' User entered 'No (N)'	System	02 Nov 2020 19:50:17
	System	02 Nov 2020 19:50:17

US3892032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

Have you been exposed to someone with 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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-11-02T12:49:54', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'c43c72db-5e20-412f-91ed-7eb7b5f5607d' User entered 'No (N)'	System	02 Nov 2020 19:50:17
	System	02 Nov 2020 19:50:17

US3892032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-11-02T12:50:15', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'c43c72db-5e20-412f-91ed-7eb7b5f5607d' User entered '02 Nov 2020 12:50:15'	System	02 Nov 2020 19:50:17
	System	02 Nov 2020 19:50:17

US3892032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	31 Aug 2020 18:17:16
User entered '31 Oct 2020 00:01'	System	31 Aug 2020 18:17:16

US3892032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	31 Aug 2020 18:17:16
User entered '04 Nov 2020 23:59'	System	31 Aug 2020 18:17:16

US3892032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	31 Aug 2020 18:17:16
User entered 'Day 71'	System	31 Aug 2020 18:17:16

US3892032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-11-10T13:12:52', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'e1ad161f-cbf7-4f6e-a463-4591c2dd4c1e' User entered 'No (N)'	System	10 Nov 2020 20:13:07
	System	10 Nov 2020 20:13:07

US3892032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

Have you been exposed to someone with 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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-11-10T13:12:55', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'e1ad161f-cbf7-4f6e-a463-4591c2dd4c1e' User entered 'No (N)'	System	10 Nov 2020 20:13:07
	System	10 Nov 2020 20:13:07

US3892032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-11-10T13:13:05', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'e1ad161f-cbf7-4f6e-a463-4591c2dd4c1e' User entered '10 Nov 2020 13:13:05'	System	10 Nov 2020 20:13:07
	System	10 Nov 2020 20:13:07

US3892032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	31 Aug 2020 18:17:16
User entered '07 Nov 2020 00:01'	System	31 Aug 2020 18:17:16

US3892032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	31 Aug 2020 18:17:16
User entered '11 Nov 2020 23:59'	System	31 Aug 2020 18:17:16

US3892032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	31 Aug 2020 18:17:16
User entered 'Day 78'	System	31 Aug 2020 18:17:16

US3892032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-11-16T19:09:30', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '277fb146-85c1-450e-9202-06328e83832d' User entered 'Yes (Y)'	System	17 Nov 2020 02:11:29
	System	17 Nov 2020 02:11:29

US3892032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

Have you been exposed to someone with 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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-11-16T19:10:11', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '277fb146-85c1-450e-9202-06328e83832d' User entered 'No (N)'	System	17 Nov 2020 02:11:29
	System	17 Nov 2020 02:11:29

US3892032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-11-16T19:10:17', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '277fb146-85c1-450e-9202-06328e83832d' User entered 'Yes (Y)'	System	17 Nov 2020 02:11:29
	System	17 Nov 2020 02:11:29

US3892032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-11-16T19:10:46', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '277fb146-85c1-450e-9202-06328e83832d' User entered '0'	System	17 Nov 2020 02:11:29
	System	17 Nov 2020 02:11:29

US3892032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-11-16T19:10:46', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '277fb146-85c1-450e-9202-06328e83832d' User entered '1'	System	17 Nov 2020 02:11:29
	System	17 Nov 2020 02:11:29

US3892032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-11-16T19:10:46', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '277fb146-85c1-450e-9202-06328e83832d' User entered '1'	System	17 Nov 2020 02:11:29
	System	17 Nov 2020 02:11:29

US3892032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-11-16T19:10:46', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '277fb146-85c1-450e-9202-06328e83832d' User entered '1'	System	17 Nov 2020 02:11:29
	System	17 Nov 2020 02:11:29

US3892032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-11-16T19:10:46', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '277fb146-85c1-450e-9202-06328e83832d' User entered '0'	System	17 Nov 2020 02:11:29
	System	17 Nov 2020 02:11:29

US3892032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-11-16T19:10:46', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '277fb146-85c1-450e-9202-06328e83832d' User entered '1'	System	17 Nov 2020 02:11:29
	System	17 Nov 2020 02:11:29

US3892032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-11-16T19:10:46', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '277fb146-85c1-450e-9202-06328e83832d' User entered '1'	System	17 Nov 2020 02:11:29
	System	17 Nov 2020 02:11:29

US3892032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-11-16T19:10:46', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '277fb146-85c1-450e-9202-06328e83832d' User entered '1'	System	17 Nov 2020 02:11:29
	System	17 Nov 2020 02:11:29

US3892032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-11-16T19:10:46', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '277fb146-85c1-450e-9202-06328e83832d' User entered '1'	System	17 Nov 2020 02:11:29
	System	17 Nov 2020 02:11:29

US3892032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-11-16T19:10:46', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '277fb146-85c1-450e-9202-06328e83832d' User entered '1'	System	17 Nov 2020 02:11:29
	System	17 Nov 2020 02:11:29

US3892032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-11-16T19:10:46', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '277fb146-85c1-450e-9202-06328e83832d' User entered '0'	System	17 Nov 2020 02:11:29
	System	17 Nov 2020 02:11:29

US3892032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-11-16T19:10:46', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '277fb146-85c1-450e-9202-06328e83832d' User entered '0'	System	17 Nov 2020 02:11:29
	System	17 Nov 2020 02:11:29

US3892032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-11-16T19:10:46', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '277fb146-85c1-450e-9202-06328e83832d' User entered '1'	System	17 Nov 2020 02:11:29
	System	17 Nov 2020 02:11:29

US3892032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-11-16T19:10:46', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '277fb146-85c1-450e-9202-06328e83832d' User entered '1'	System	17 Nov 2020 02:11:29
	System	17 Nov 2020 02:11:29

US3892032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-11-16T19:10:46', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '277fb146-85c1-450e-9202-06328e83832d' User entered '1'	System	17 Nov 2020 02:11:29
	System	17 Nov 2020 02:11:29

US3892032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-11-16T19:10:46', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '277fb146-85c1-450e-9202-06328e83832d' User entered '0'	System	17 Nov 2020 02:11:29
	System	17 Nov 2020 02:11:29

US3892032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-11-16T19:10:46', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '277fb146-85c1-450e-9202-06328e83832d' User entered '0'	System	17 Nov 2020 02:11:29
	System	17 Nov 2020 02:11:29

US3892032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Please 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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-11-16T19:10:54', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '277fb146-85c1-450e-9202-06328e83832d'	System	17 Nov 2020 02:11:29
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Nov 2020 02:11:29

US3892032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[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 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-11-16T19:11:11', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '277fb146-85c1-450e-9202-06328e83832d'	System	17 Nov 2020 02:11:29
User entered 'No (N)'	System	17 Nov 2020 02:11:29

US3892032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-11-16T19:11:20', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '277fb146-85c1-450e-9202-06328e83832d' User entered '16 Nov 2020 19:11:20'	System	17 Nov 2020 02:11:29
	System	17 Nov 2020 02:11:29

US3892032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	31 Aug 2020 18:17:16
User entered '14 Nov 2020 00:01'	System	31 Aug 2020 18:17:16

US3892032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:49
Data entry locked.	System	31 Aug 2020 18:17:16
User entered '18 Nov 2020 23:59'	System	31 Aug 2020 18:17:16

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-12-02T00:42:33', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'ab9ced61-631e-4ed7-934b-b1a27163ab65' User entered 'No (N)'	System	02 Dec 2020 07:42:52
	System	02 Dec 2020 07:42:52

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Have you been exposed to someone with 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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-12-02T00:42:41', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'ab9ced61-631e-4ed7-934b-b1a27163ab65' User entered 'No (N)'	System	02 Dec 2020 07:42:52

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-12-02T00:42:48', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'ab9ced61-631e-4ed7-934b-b1a27163ab65' User entered '02 Dec 2020 00:42:48'	System	02 Dec 2020 07:42:52
	System	02 Dec 2020 07:42:52

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-12-11T12:00:21', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '5c4a9a35-9e12-43af-8682-2c4e8309eacc' User entered 'No (N)'	System	11 Dec 2020 19:00:44
	System	11 Dec 2020 19:00:44

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Have you been exposed to someone with 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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-12-11T12:00:29', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '5c4a9a35-9e12-43af-8682-2c4e8309eacc'	System	11 Dec 2020 19:00:44
User entered 'No (N)'	System	11 Dec 2020 19:00:44

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-12-11T12:00:38', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '5c4a9a35-9e12-43af-8682-2c4e8309eacc' User entered '11 Dec 2020 12:00:38'	System	11 Dec 2020 19:00:44
	System	11 Dec 2020 19:00:44

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-12-16T00:02:13', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '73fb0830-9f2a-48b3-9905-aa915922fcab' User entered 'No (N)'	System	16 Dec 2020 07:02:39
	System	16 Dec 2020 07:02:39

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

Have you been exposed to someone with 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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-12-16T00:02:25', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '73fb0830-9f2a-48b3-9905-aa915922fcab' User entered 'No (N)'	System	16 Dec 2020 07:02:39
	System	16 Dec 2020 07:02:39

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-12-16T00:02:35', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '73fb0830-9f2a-48b3-9905-aa915922fcab' User entered '16 Dec 2020 00:02:35'	System	16 Dec 2020 07:02:39
	System	16 Dec 2020 07:02:39

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-12-23T13:38:06', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'f6ae5379-21a3-42a6-bc5f-d8214621b2e5' User entered 'No (N)'	System	23 Dec 2020 20:38:24
	System	23 Dec 2020 20:38:24

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

Have you been exposed to someone with 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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-12-23T13:38:15', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'f6ae5379-21a3-42a6-bc5f-d8214621b2e5' User entered 'No (N)'	System	23 Dec 2020 20:38:24
	System	23 Dec 2020 20:38:24

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-12-23T13:38:22', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'f6ae5379-21a3-42a6-bc5f-d8214621b2e5' User entered '23 Dec 2020 13:38:22'	System	23 Dec 2020 20:38:24
	System	23 Dec 2020 20:38:24

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-12-30T00:06:40', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'dbb6593d-ead7-4605-883c-786fd1e21eef' User entered 'No (N)'	System	30 Dec 2020 07:06:57
	System	30 Dec 2020 07:06:57

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

Have you been exposed to someone with 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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-12-30T00:06:45', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'dbb6593d-ead7-4605-883c-786fd1e21eef' User entered 'No (N)'	System	30 Dec 2020 07:06:57

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2020-12-30T00:06:54', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'dbb6593d-ead7-4605-883c-786fd1e21eef' User entered '30 Dec 2020 00:06:54'	System	30 Dec 2020 07:06:57
	System	30 Dec 2020 07:06:57

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-01-06T00:01:17', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7843ed53-2881-442f-a8b2-5afffc2a8459' User entered 'No (N)'	System	06 Jan 2021 07:01:35
	System	06 Jan 2021 07:01:35

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

Have you been exposed to someone with 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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-01-06T00:01:22', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7843ed53-2881-442f-a8b2-5afffc2a8459' User entered 'No (N)'	System	06 Jan 2021 07:01:35
	System	06 Jan 2021 07:01:35

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-01-06T00:01:28', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7843ed53-2881-442f-a8b2-5afffc2a8459' User entered '06 Jan 2021 00:01:28'	System	06 Jan 2021 07:01:35
	System	06 Jan 2021 07:01:35

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-01-13T00:03:31', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'd1cb9492-48d1-427e-8c36-1ad37edc51df' User entered 'Yes (Y)'	System	13 Jan 2021 07:04:55
	System	13 Jan 2021 07:04:55

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

Have you been exposed to someone with 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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-01-13T00:03:36', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'd1cb9492-48d1-427e-8c36-1ad37edc51df' User entered 'No (N)'	System	13 Jan 2021 07:04:55

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-01-13T00:03:49', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'd1cb9492-48d1-427e-8c36-1ad37edc51df' User entered 'No (N)'	System	13 Jan 2021 07:04:55
	System	13 Jan 2021 07:04:55

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-01-13T00:04:44', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'd1cb9492-48d1-427e-8c36-1ad37edc51df' User entered 'No (N)'	System	13 Jan 2021 07:04:55
	System	13 Jan 2021 07:04:55

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-01-13T00:04:50', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'd1cb9492-48d1-427e-8c36-1ad37edc51df' User entered '13 Jan 2021 00:04:50'	System	13 Jan 2021 07:04:55
	System	13 Jan 2021 07:04:55

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-01-20T08:31:18', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'c50bdeb4-d111-42d8-a8dd-dce183450eb9'	System	20 Jan 2021 15:31:49
User entered 'No (N)'	System	20 Jan 2021 15:31:49

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

Have you been exposed to someone with 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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-01-20T08:31:24', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'c50bdeb4-d111-42d8-a8dd-dce183450eb9'	System	20 Jan 2021 15:31:49
User entered 'No (N)'	System	20 Jan 2021 15:31:49

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-01-20T08:31:44', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'c50bdeb4-d111-42d8-a8dd-dce183450eb9' User entered '20 Jan 2021 08:31:44'	System	20 Jan 2021 15:31:49

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-01-30T17:59:20', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '581834b7-0577-448a-b98f-42c069a7b60e'	System	31 Jan 2021 00:59:31
User entered 'No (N)'	System	31 Jan 2021 00:59:31

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

Have you been exposed to someone with 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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-01-30T17:59:24', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '581834b7-0577-448a-b98f-42c069a7b60e' User entered 'No (N)'	System	31 Jan 2021 00:59:31

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-01-30T17:59:29', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '581834b7-0577-448a-b98f-42c069a7b60e'	System	31 Jan 2021 00:59:31
User entered '30 Jan 2021 17:59:29'	System	31 Jan 2021 00:59:31

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-02-06T18:01:58', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'ad3fef96-03d8-4b24-a09e-fe746d05f27a' User entered 'No (N)'	System	07 Feb 2021 01:02:15
	System	07 Feb 2021 01:02:15

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

Have you been exposed to someone with 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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-02-06T18:02:03', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'ad3fef96-03d8-4b24-a09e-fe746d05f27a' User entered 'No (N)'	System	07 Feb 2021 01:02:15

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-02-06T18:02:08', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'ad3fef96-03d8-4b24-a09e-fe746d05f27a' User entered '06 Feb 2021 18:02:08'	System	07 Feb 2021 01:02:15
	System	07 Feb 2021 01:02:15

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-02-10T05:46:36', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'efa8864a-aeef-4233-bca1-bd1dd107da12'	System	10 Feb 2021 12:47:10
User entered 'No (N)'	System	10 Feb 2021 12:47:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

Have you been exposed to someone with 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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-02-10T05:46:50', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'efa8864a-aeef-4233-bca1-bd1dd107da12'	System	10 Feb 2021 12:47:10
User entered 'No (N)'	System	10 Feb 2021 12:47:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-02-10T05:47:08', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'efa8864a-ae4e-4233-bca1-bd1dd107da12'	System	10 Feb 2021 12:47:10
User entered '10 Feb 2021 05:47:08'	System	10 Feb 2021 12:47:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-02-17T00:02:51', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '809033b8-4cd4-457b-8754-1be403308ce7'	System	17 Feb 2021 07:03:38
User entered 'No (N)'	System	17 Feb 2021 07:03:38

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

Have you been exposed to someone with 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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-02-17T00:03:29', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '809033b8-4cd4-457b-8754-1be403308ce7'	System	17 Feb 2021 07:03:38
User entered 'No (N)'	System	17 Feb 2021 07:03:38

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-02-17T00:03:35', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '809033b8-4cd4-457b-8754-1be403308ce7'	System	17 Feb 2021 07:03:38
User entered '17 Feb 2021 00:03:35'	System	17 Feb 2021 07:03:38

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-02-24T00:01:39-07:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '271631f4-c0b6-4c08-a07a-f219e5cfd7f7'	System	24 Feb 2021 07:01:59
User entered 'No (N)'	System	24 Feb 2021 07:01:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

Have you been exposed to someone with 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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-02-24T00:01:46-07:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '271631f4-c0b6-4c08-a07a-f219e5cfd7f7'	System	24 Feb 2021 07:01:59
User entered 'No (N)'	System	24 Feb 2021 07:01:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-02-24T00:01:57-07:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '271631f4-c0b6-4c08-a07a-f219e5cfd7f7'	System	24 Feb 2021 07:01:59
User entered '24 Feb 2021 07:01:57'	System	24 Feb 2021 07:01:59

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-03-03T00:02:31-07:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '76870f74-bdee-4dc1-99ef-40408fb2453b'	System	03 Mar 2021 07:02:45
User entered 'No (N)'	System	03 Mar 2021 07:02:45

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

Have you been exposed to someone with 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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-03-03T00:02:36-07:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '76870f74-bdee-4dc1-99ef-40408fb2453b'	System	03 Mar 2021 07:02:45
User entered 'No (N)'	System	03 Mar 2021 07:02:45

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-03-03T00:02:41-07:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '76870f74-bdee-4dc1-99ef-40408fb2453b' User entered '03 Mar 2021 00:02:41'	System	03 Mar 2021 07:02:45
	System	03 Mar 2021 07:02:45

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-03-10T00:02:36-07:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7663019b-3a04-4e10-89a9-603d81cc8ad9' User entered 'No (N)'	System	10 Mar 2021 07:02:51
	System	10 Mar 2021 07:02:51

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

Have you been exposed to someone with 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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-03-10T00:02:41-07:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7663019b-3a04-4e10-89a9-603d81cc8ad9' User entered 'No (N)'	System	10 Mar 2021 07:02:51

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-03-10T00:02:48-07:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7663019b-3a04-4e10-89a9-603d81cc8ad9' User entered '10 Mar 2021 00:02:48'	System	10 Mar 2021 07:02:51
	System	10 Mar 2021 07:02:51

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-03-17T03:54:00-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7f4df6af-8d90-4cc0-8c19-58a95558ebffc'	System	17 Mar 2021 09:54:27
User entered 'No (N)'	System	17 Mar 2021 09:54:27

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

Have you been exposed to someone with 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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-03-17T03:54:10-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7f4df6af-8d90-4cc0-8c19-58a9558ebffc'	System	17 Mar 2021 09:54:27
User entered 'No (N)'	System	17 Mar 2021 09:54:27

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-03-17T03:54:23-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7f4df6af-8d90-4cc0-8c19-58a9558ebffc'	System	17 Mar 2021 09:54:27
User entered '17 Mar 2021 03:54:23'	System	17 Mar 2021 09:54:27

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-03-24T01:20:27-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '0d2341e3-2bf2-4dea-9278-d0deeb54765d' User entered 'No (N)'	System	24 Mar 2021 07:20:42
	System	24 Mar 2021 07:20:42

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

Have you been exposed to someone with 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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-03-24T01:20:32-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '0d2341e3-2bf2-4dea-9278-d0deeb54765d' User entered 'No (N)'	System	24 Mar 2021 07:20:42

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-03-24T01:20:37-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '0d2341e3-2bf2-4dea-9278-d0deeb54765d' User entered '24 Mar 2021 01:20:37'	System	24 Mar 2021 07:20:42
	System	24 Mar 2021 07:20:42

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-03-31T00:47:53-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '18df6912-01b3-46c8-9dee-cd74500f83bc'	System	31 Mar 2021 06:48:06
User entered 'No (N)'	System	31 Mar 2021 06:48:06

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Have you been exposed to someone with 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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-03-31T00:47:59-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '18df6912-01b3-46c8-9dee-cd74500f83bc'	System	31 Mar 2021 06:48:06
User entered 'No (N)'	System	31 Mar 2021 06:48:06

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-03-31T00:48:04-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '18df6912-01b3-46c8-9dee-cd74500f83bc' User entered '31 Mar 2021 00:48:04'	System	31 Mar 2021 06:48:06
	System	31 Mar 2021 06:48:06

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-04-08T08:06:01-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '60e9467e-3db5-4936-920a-412aad6e02d1'	System	08 Apr 2021 14:06:12
User entered 'No (N)'	System	08 Apr 2021 14:06:12

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Have you been exposed to someone with 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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-04-08T08:06:05-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '60e9467e-3db5-4936-920a-412aad6e02d1'	System	08 Apr 2021 14:06:12
User entered 'No (N)'	System	08 Apr 2021 14:06:12

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-04-08T08:06:09-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '60e9467e-3db5-4936-920a-412aad6e02d1'	System	08 Apr 2021 14:06:12
User entered '08 Apr 2021 08:06:09'	System	08 Apr 2021 14:06:12

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-04-16T16:26:06-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'eb30bf60-508d-4721-8795-13a506a8dddf' User entered 'No (N)'	System	16 Apr 2021 22:26:21
	System	16 Apr 2021 22:26:21

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Have you been exposed to someone with 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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-04-16T16:26:09-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'eb30bf60-508d-4721-8795-13a506a8dddf' User entered 'No (N)'	System	16 Apr 2021 22:26:21
	System	16 Apr 2021 22:26:21

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-04-16T16:26:18-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'eb30bf60-508d-4721-8795-13a506a8dddf' User entered '16 Apr 2021 16:26:18'	System	16 Apr 2021 22:26:21
	System	16 Apr 2021 22:26:21

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-04-21T09:33:46-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'c05fcd0d-9a1a-4823-8c2f-d84fcf3f2907'	System	21 Apr 2021 15:34:11
User entered 'No (N)'	System	21 Apr 2021 15:34:11

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

Have you been exposed to someone with 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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-04-21T09:33:50-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'c05fcd0d-9a1a-4823-8c2f-d84fcf3f2907'	System	21 Apr 2021 15:34:11
User entered 'No (N)'	System	21 Apr 2021 15:34:11

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-04-21T09:34:03-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: 'c05fcd0d-9a1a-4823-8c2f-d84fcf3f2907'	System	21 Apr 2021 15:34:11
User entered '21 Apr 2021 09:34:03'	System	21 Apr 2021 15:34:11

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-04-28T02:04:09-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7a644e4a-c2fe-4209-90d0-a0144797ef95'	System	29 Apr 2021 01:09:45
User entered 'Yes (Y)'	System	29 Apr 2021 01:09:45

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

Have you been exposed to someone with 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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-04-28T02:04:42-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7a644e4a-c2fe-4209-90d0-a0144797ef95'	System	29 Apr 2021 01:09:45
User entered 'Yes (Y)'	System	29 Apr 2021 01:09:45

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-04-28T02:05:00-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7a644e4a-c2fe-4209-90d0-a0144797ef95'	System	29 Apr 2021 01:09:45
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Apr 2021 01:09:45

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-04-28T02:06:07-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7a644e4a-c2fe-4209-90d0-a0144797ef95'	System	29 Apr 2021 01:09:45
User entered 'Yes (Y)'	System	29 Apr 2021 01:09:45

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-04-28T02:06:58-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7a644e4a-c2fe-4209-90d0-a0144797ef95'	System	29 Apr 2021 01:09:45
User entered '0'	System	29 Apr 2021 01:09:45

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-04-28T02:06:58-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7a644e4a-c2fe-4209-90d0-a0144797ef95'	System	29 Apr 2021 01:09:45
User entered '1'	System	29 Apr 2021 01:09:45

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-04-28T02:06:58-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7a644e4a-c2fe-4209-90d0-a0144797ef95'	System	29 Apr 2021 01:09:45
User entered '0'	System	29 Apr 2021 01:09:45

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-04-28T02:06:58-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7a644e4a-c2fe-4209-90d0-a0144797ef95'	System	29 Apr 2021 01:09:45
User entered '0'	System	29 Apr 2021 01:09:45

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-04-28T02:06:58-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7a644e4a-c2fe-4209-90d0-a0144797ef95'	System	29 Apr 2021 01:09:45
User entered '0'	System	29 Apr 2021 01:09:45

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-04-28T02:06:58-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7a644e4a-c2fe-4209-90d0-a0144797ef95'	System	29 Apr 2021 01:09:45
User entered '0'	System	29 Apr 2021 01:09:45

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-04-28T02:06:58-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7a644e4a-c2fe-4209-90d0-a0144797ef95'	System	29 Apr 2021 01:09:45
User entered '0'	System	29 Apr 2021 01:09:45

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-04-28T02:06:58-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7a644e4a-c2fe-4209-90d0-a0144797ef95'	System	29 Apr 2021 01:09:45
User entered '0'	System	29 Apr 2021 01:09:45

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-04-28T02:06:58-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7a644e4a-c2fe-4209-90d0-a0144797ef95'	System	29 Apr 2021 01:09:45
User entered '0'	System	29 Apr 2021 01:09:45

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-04-28T02:06:58-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7a644e4a-c2fe-4209-90d0-a0144797ef95'	System	29 Apr 2021 01:09:45
User entered '0'	System	29 Apr 2021 01:09:45

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-04-28T02:06:58-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7a644e4a-c2fe-4209-90d0-a0144797ef95'	System	29 Apr 2021 01:09:45
User entered '0'	System	29 Apr 2021 01:09:45

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-04-28T02:06:58-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7a644e4a-c2fe-4209-90d0-a0144797ef95'	System	29 Apr 2021 01:09:45
User entered '0'	System	29 Apr 2021 01:09:45

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-04-28T02:06:58-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7a644e4a-c2fe-4209-90d0-a0144797ef95'	System	29 Apr 2021 01:09:45
User entered '0'	System	29 Apr 2021 01:09:45

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-04-28T02:06:58-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7a644e4a-c2fe-4209-90d0-a0144797ef95'	System	29 Apr 2021 01:09:45
User entered '0'	System	29 Apr 2021 01:09:45

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-04-28T02:06:58-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7a644e4a-c2fe-4209-90d0-a0144797ef95'	System	29 Apr 2021 01:09:45
User entered '0'	System	29 Apr 2021 01:09:45

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-04-28T02:06:58-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7a644e4a-c2fe-4209-90d0-a0144797ef95'	System	29 Apr 2021 01:09:45
User entered '0'	System	29 Apr 2021 01:09:45

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-04-28T02:06:58-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7a644e4a-c2fe-4209-90d0-a0144797ef95'	System	29 Apr 2021 01:09:45
User entered '0'	System	29 Apr 2021 01:09:45

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-04-28T02:08:04-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7a644e4a-c2fe-4209-90d0-a0144797ef95'	System	29 Apr 2021 01:09:45
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Apr 2021 01:09:45

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[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 (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-04-28T02:08:40-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7a644e4a-c2fe-4209-90d0-a0144797ef95'	System	29 Apr 2021 01:09:45
User entered 'Yes (Y)'	System	29 Apr 2021 01:09:45

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-04-28T02:09:13-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7a644e4a-c2fe-4209-90d0-a0144797ef95'	System	29 Apr 2021 01:09:45
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Apr 2021 01:09:45

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-04-28T02:09:35-06:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '7a644e4a-c2fe-4209-90d0-a0144797ef95'	System	29 Apr 2021 01:09:45
User entered '28 Apr 2021 02:09:35'	System	29 Apr 2021 01:09:45

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '19 Oct 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '23 Oct 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '26 Oct 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '30 Oct 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '02 Nov 2022 00:01'	System	19 Nov 2020 20:59:10

US3892032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:59:10
Amendment Manager: User entered '06 Nov 2022 23:59'	System	19 Nov 2020 20:59:10

US3892032

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:18:29

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 21:08:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-03-01T16:01:42-07:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '48fe5c47-4153-44b9-80b7-25dc6c80a0d5'	System	01 Mar 2021 23:06:17
User entered 'Yes (Y)'	System	01 Mar 2021 23:06:17

US3892032

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:18:29

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?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:08:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-03-01T16:01:51-07:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '48fe5c47-4153-44b9-80b7-25dc6c80a0d5'	System	01 Mar 2021 23:06:17
User entered 'No (N)'	System	01 Mar 2021 23:06:17

US3892032

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:18:29

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:08:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CD9648E-0DCC-40C3-BA72-E76BCFC06724)', Time: '2021-03-01T16:02:13-07:00', User OID: 'PatientReportedOutcome (US3892032)', ODM File OID: '48fe5c47-4153-44b9-80b7-25dc6c80a0d5'	System	01 Mar 2021 23:06:17
User entered '01 Mar 2021 16:02:13'	System	01 Mar 2021 23:06:17

US3892032

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:55:02
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	20 Nov 2020 22:57:15

US3892032

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:55:02
User entered '20 Nov 2020'	Andryelle Toledo (b) (4)	20 Nov 2020 22:57:15

US3892032

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:55:02
User entered 'Contact Made (CONTACT MADE)'	Andryelle Toledo (b) (4) (b) (4)	20 Nov 2020 22:57:15

US3892032

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:55:02
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	20 Nov 2020 22:57:15

US3892032

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:55:08
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	20 Nov 2020 22:57:22

US3892032

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:03
User entered 'I'	System	20 Nov 2020 22:57:22

US3892032

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:46:44
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 19:10:18
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	28 Dec 2020 20:07:25

US3892032

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:46:44
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:10:18
User entered '28 Dec 2020'	Andryelle Toledo (b) (4) (b) (4)	28 Dec 2020 20:07:25

US3892032

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:46:44
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:10:18
User entered 'Contact Made (CONTACT MADE)'	Andryelle Toledo (b) (4) (b) (4)	28 Dec 2020 20:07:25

US3892032

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:46:44
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:10:18
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	28 Dec 2020 20:07:25

US3892032

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:46:44
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:11:08
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	28 Dec 2020 20:07:29

US3892032

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:46:44
User entered 'I'	System	28 Dec 2020 20:07:29

US3892032

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:46:44
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:27:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 22:28:00

US3892032

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:46:44
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:27:36
User entered '25 Jan 2021'	(b) (4), (b) (6)	25 Jan 2021 22:28:00

US3892032

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:46:44
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:27:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	25 Jan 2021 22:28:00

US3892032

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:46:44
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:27:36
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 22:28:00

US3892032

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:46:44
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:28:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 22:28:04

US3892032

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:46:44
User entered 'I'	System	25 Jan 2021 22:28:04

US3892032

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:46:44
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:45:12
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Yes (Y)'	(b) (4) Courtney Jensen (b) (4) (b) (4)	22 Feb 2021 21:34:40

US3892032

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:46:44
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:45:12
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '22 Feb 2021'	(b) (4) Courtney Jensen (b) (4) (b) (4)	22 Feb 2021 21:34:40

US3892032

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:46:44
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:45:12
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Courtney Jensen (b) (4) (b) (4)	22 Feb 2021 21:34:40

US3892032

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:46:44
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:45:12
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	(b) (4) Courtney Jensen (b) (4) (b) (4)	22 Feb 2021 21:34:40

US3892032

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:46:44
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:45:22
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Yes (Y)'	(b) (4) Courtney Jensen (b) (4) (b) (4)	22 Feb 2021 21:34:46

US3892032

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:46:44
User entered 'I'	System	22 Feb 2021 21:34:46

US3892032

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:50:06
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	06 Apr 2021 17:22:39

US3892032

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:50:06
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered '06 Apr 2021'	Andryelle Toledo (b) (4)	06 Apr 2021 17:22:39

US3892032

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:50:06
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered 'Clinic (Clinic)'	Andryelle Toledo (b) (4)	06 Apr 2021 17:22:39

US3892032

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	06 Apr 2021 17:22:39

US3892032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:50:18
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered 'No (N)'	Andryelle Toledo (b) (4)	06 Apr 2021 17:22:45

US3892032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:50:18
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered empty.	Andryelle Toledo (b) (4)	06 Apr 2021 17:22:45

US3892032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:50:18
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered empty.	Andryelle Toledo (b) (4)	06 Apr 2021 17:22:45

US3892032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 17:22:45

US3892032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:50:18
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered empty.	Andryelle Toledo (b) (4)	06 Apr 2021 17:22:45

US3892032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:50:18
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered empty.	Andryelle Toledo (b) (4)	06 Apr 2021 17:22:45

US3892032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:50:18
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered empty.	Andryelle Toledo (b) (4)	06 Apr 2021 17:22:45

US3892032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:50:18
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered empty.	Andryelle Toledo (b) (4)	06 Apr 2021 17:22:45

US3892032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 17:22:45

US3892032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:50:18
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered empty.	Andryelle Toledo (b) (4)	06 Apr 2021 17:22:45

US3892032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 17:22:45

US3892032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:50:18
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered empty.	Andryelle Toledo (b) (4)	06 Apr 2021 17:22:45

US3892032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 17:22:45

US3892032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:50:18
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered empty.	Andryelle Toledo (b) (4)	06 Apr 2021 17:22:45

US3892032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 17:22:45

US3892032

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:18:29

Was the physical examination performed?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:16
User closed query 'Kindly confirm if this was completed, per source, this is not clearly noted. Thank you.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 20:58:10
Query 'Kindly confirm if this was completed, per source, this is not clearly noted. Thank you.' answered with 'Update' (Site from CRA).	Andryelle Toledo (b) (4)	12 Apr 2021 20:37:27
User opened query 'Kindly confirm if this was completed, per source, this is not clearly noted. Thank you.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 17:51:33
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	06 Apr 2021 17:22:54

US3892032

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:18:29

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:16
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered '06 Apr 2021'	Andryelle Toledo (b) (4)	06 Apr 2021 17:22:54

US3892032

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:51:47
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	06 Apr 2021 17:23:03

US3892032

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:51:47
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered '06 Apr 2021'	(b) (4) Andryelle Toledo (b) (4)	06 Apr 2021 17:23:03

US3892032

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:51:47
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered '10:30'	Andryelle Toledo (b) (4)	06 Apr 2021 17:23:03

US3892032

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
User entered '06 Apr 2021 10:30'	System	06 Apr 2021 17:23:03

US3892032

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:50:11
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	06 Apr 2021 17:23:07

US3892032

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:29

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 17:23:07

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:18:29

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:52:57
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 03OCT2020 for Day 21 is reported under Illness visit in PPD central lab, however saliva log is not completed in EDC. Please complete, else clarify. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 12:11:25
Query 'Per GCL Lab Recon: Saliva: Sample dated 03OCT2020 for Day 21 is reported under Illness visit in PPD central lab, however saliva log is not completed in EDC. Please complete, else clarify. Thank you.' answered with 'Illness visit update and saliva samples dates completed' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	02 Dec 2020 02:20:47
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 03OCT2020 for Day 21 is reported under Illness visit in PPD central lab, however saliva log is not completed in EDC. Please complete, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 11:03:43
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:12:58
User entered '01 Oct 2020'	Andryelle Toledo (b) (4) (b) (4)	05 Oct 2020 20:40:19

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:18:29

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:52:57
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 11:48:41
	(b) (4), (b) (6)	28 Oct 2020 19:12:58
Query 'Data is required. Please complete.' answered with 'Time is UNK' (Site from System).	Andryelle Toledo (b) (4)	21 Oct 2020 12:58:11
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	05 Oct 2020 20:40:19
	Andryelle Toledo (b) (4)	05 Oct 2020 20:40:19
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:18:29

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:52:57
User entered empty.	System	05 Oct 2020 20:40:19

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:18:29

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:52:57
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 20:05:00
User closed query 'Type of Contact should be noted a "Safety Call" kindly consider updating EDC with this type of contact. Thank you.' (Site from CRA).	(b) (4), (b) (6)	08 Dec 2020 20:04:58
Query 'Type of Contact should be noted a "Safety Call" kindly consider updating EDC with this type of contact. Thank you.' answered with 'update' (Site from CRA).	Andryelle Toledo (b) (4) (b) (4)	02 Dec 2020 02:18:06
DataPoint Un-verified.	Andryelle Toledo (b) (4) (b) (4)	02 Dec 2020 02:17:39
User entered 'Safety Call (Safety Call)' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	02 Dec 2020 02:17:39
User opened query 'Type of Contact should be noted a "Safety Call" kindly consider updating EDC with this type of contact. Thank you.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 18:53:08
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:12:58
User entered 'Convalescent Tele-visit (Convalescent Tele-visit)'	Andryelle Toledo (b) (4) (b) (4)	05 Oct 2020 20:40:19

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:18:29

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:52:57
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:12:58
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	05 Oct 2020 20:40:19

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Day 1 (Day 1)'	(b) (4) Andryelle Toledo (b) (4)	21 Oct 2020 13:08:11

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '28 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:28:51
User entered '29 Sep 2020'	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 13:08:11
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:36:20
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:28:51
User entered '1'	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 13:08:11
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 13:08:11

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User entered empty.	System	21 Oct 2020 13:08:11

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 13:08:11

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty; reason for change Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:36:20
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:28:51
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 13:08:11
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty; reason for change Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:36:20
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:28:51
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 13:08:11
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty; reason for change Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:36:20
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:28:51
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 13:08:11
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty; reason for change Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:36:20
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:28:51
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 13:08:11
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty; reason for change Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:36:20
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:28:51
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 13:08:11
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty; reason for change Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:36:20
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:28:51
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 13:08:11
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty; reason for change Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:36:20
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:28:51
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 13:08:11
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty; reason for change Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:36:20
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:28:51
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 13:08:11
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty; reason for change Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:36:20
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:28:51
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 13:08:11
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty; reason for change Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:36:20
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:28:51
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 13:08:11
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty; reason for change Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:36:20
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:28:51
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 13:08:11
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty; reason for change Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:36:20
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:28:51
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 13:08:11
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty; reason for change Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:36:20
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:28:51
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 13:08:11
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty; reason for change Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:36:20
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:28:51
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 13:08:11
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty; reason for change Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:36:20
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:28:51
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 13:08:11
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty; reason for change Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:36:20
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:29:13
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 13:08:11
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Day 2 (Day 2)'	(b) (4) Andryelle Toledo (b) (4)	21 Oct 2020 13:09:06

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '29 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:29:13
User entered '30 Sep 2020'	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 13:09:06
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'l'	Andryelle Toledo (b) (4)	21 Oct 2020 13:09:06

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 13:09:06
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User entered empty.	System	21 Oct 2020 13:09:06

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 13:09:06

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 13:09:06

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 13:09:06

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 13:09:06

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 13:09:06

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 13:09:06

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 13:09:06

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 13:09:06
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 13:09:06
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 13:09:06

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 13:09:06

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 13:09:06

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 13:09:06

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 13:09:06
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 13:09:06

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 13:09:06

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 13:09:06

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Day 3 (Day 3)'	(b) (4) Andryelle Toledo (b) (4)	21 Oct 2020 13:09:06

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '01 Oct 2020'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 13:09:06

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'l'	Andryelle Toledo (b) (4)	21 Oct 2020 13:09:06

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 13:09:06

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User entered empty.	System	21 Oct 2020 13:09:06

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 13:09:06

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 13:09:06

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 13:09:06
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 13:09:06

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 13:09:06

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 13:09:06
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 13:09:06

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 13:09:06

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 13:09:06

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 13:09:06

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 13:09:06

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 13:09:06
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 13:09:06

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 13:09:06
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 13:09:06

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 13:09:06

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	(b) (4)	21 Oct 2020 13:09:06
	Andryelle Toledo (b) (4)	
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Day 4 (Day 4)' reason for change:	(b) (4)	
Data Entry Error	Andryelle Toledo (b) (4)	21 Oct 2020 14:38:29
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:28:51
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Oct 2020 14:38:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 14:38:29
User entered '02 Oct 2020' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	21 Oct 2020 14:38:29
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	21 Oct 2020 14:28:51
	Andryelle Toledo (b) (4)	21 Oct 2020 14:28:51
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '0'	Andryelle Toledo (b) (4)	21 Oct 2020 14:28:51

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Per CDM: It appears that O2 Saturation was not collected for Day 4. If not collected, please consider recording this as Not Done. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Jan 2021 05:33:43
Query 'Per CDM: It appears that O2 Saturation was not collected for Day 4. If not collected, please consider recording this as Not Done. ' answered with 'update' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	14 Jan 2021 18:46:15
User entered missing code ND - Not Done; reason for change Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	14 Jan 2021 18:45:48
User opened query 'Per CDM: It appears that O2 Saturation was not collected for Day 4. If not collected, please consider recording this as Not Done. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 18:17:11
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:28:51

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User entered '%'	System	14 Jan 2021 18:45:48
User entered empty.	System	21 Oct 2020 14:28:51

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '98.6' F reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:38:29
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:28:51
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 14:38:29
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 14:28:51
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:38:29
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:28:51
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 14:38:29
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 14:28:51
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 14:38:29
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 14:28:51
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 14:38:29
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 14:28:51
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:38:29
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:28:51
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 14:38:29
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 14:28:51
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 14:38:29
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 14:28:51
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 14:38:29
	(b) (4)	21 Oct 2020 14:28:51

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 14:38:29
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 14:28:51
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:38:29
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:28:51
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 14:38:29
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 14:28:51
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:38:29
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:28:51
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 14:38:29
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 14:28:51
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 14:38:29
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 14:28:51
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 14:38:29
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 14:28:51
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Day 5 (Day 5)'	(b) (4) Andryelle Toledo (b) (4)	21 Oct 2020 14:41:11

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '03 Oct 2020'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:41:11

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '0'	Andryelle Toledo (b) (4)	21 Oct 2020 14:41:11

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '98'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:41:11

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User entered '%'	System	21 Oct 2020 14:41:11

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '98.4' F	Andryelle Toledo (b) (4)	21 Oct 2020 14:41:11

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:41:11

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:41:11

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:41:11

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:41:11

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Severe (Severe)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:41:11

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:41:11

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:41:11

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:41:11

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:41:11

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:41:11

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:41:11

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:41:11

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:41:11

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:41:11

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:41:11

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:41:11

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:18:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Day 6 (Day 6)'	(b) (4) Andryelle Toledo (b) (4)	21 Oct 2020 14:42:40

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:18:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '04 Oct 2020'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:42:40

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:18:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '0'	Andryelle Toledo (b) (4)	21 Oct 2020 14:42:40

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '97'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:42:40

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User entered '%'	System	21 Oct 2020 14:42:40

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:18:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '97.4' F	Andryelle Toledo (b) (4)	21 Oct 2020 14:42:40

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:18:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:42:40

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:18:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:42:40

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:18:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:42:40

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:18:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:42:40

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:18:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:42:40

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:18:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:42:40

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:18:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:42:40

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:18:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:42:40

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:42:40

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:42:40

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:18:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:42:40

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:18:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:42:40

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:18:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:42:40

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:18:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:42:40

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:18:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:42:40

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:18:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:42:40

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:18:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Day 7 (Day 7)'	(b) (4) Andryelle Toledo (b) (4)	21 Oct 2020 14:44:01

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:18:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '05 Oct 2020'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:44:01

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:18:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '0'	Andryelle Toledo (b) (4)	21 Oct 2020 14:44:01

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '95' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 14:44:12
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 14:44:01
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User entered '%'	System	21 Oct 2020 14:44:12
User entered empty.	System	21 Oct 2020 14:44:01

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:18:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '98.4' F reason for change: Data Entry Error	(b) (4)	21 Oct 2020 14:44:12
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 14:44:01
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:18:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:44:01

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:18:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:44:01

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:18:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:44:01

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:18:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:44:01

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:18:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:44:01

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:18:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:44:01

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:18:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:44:01

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:18:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:44:01

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:44:01

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:44:01

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:18:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:44:01

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:18:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:44:01

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:18:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:44:01

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:18:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:44:01

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:18:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:44:01

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:18:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:44:01

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:18:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Day 8 (Day 8)'	(b) (4) Andryelle Toledo (b) (4)	21 Oct 2020 14:45:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:18:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:02:25
User entered '06 Oct 2020'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:45:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:18:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:02:50
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:45:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:02:51
User entered '99'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:45:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User entered '%'	System	21 Oct 2020 14:45:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:18:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:02:53
User entered '97.2' F	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:45:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:18:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:02:57
User entered 'None (None)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:45:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:18:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:02:59
User entered 'None (None)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:45:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:18:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:03:02
User entered 'Moderate (Moderate)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:45:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:18:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:03:05
User entered 'Moderate (Moderate)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:45:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:18:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:03:13
User entered 'Moderate (Moderate)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:45:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:18:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:03:17
User entered 'Moderate (Moderate)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:45:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:18:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:03:25
User entered 'Moderate (Moderate)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:45:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:18:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:03:31
User entered 'Moderate (Moderate)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:45:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:03:35
User entered 'Mild (Mild)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:45:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:03:38
User entered 'Mild (Mild)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:45:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:18:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:03:46
User entered 'None (None)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:45:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:18:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:03:53
User entered 'None (None)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:45:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:18:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:03:57
User entered 'Mild (Mild)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:45:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:18:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:04:00
User entered 'None (None)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:45:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:18:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:04:08
User entered 'None (None)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:45:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:18:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:04:06
User entered 'None (None)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:45:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:18:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Day 9 (Day 9)'	(b) (4) Andryelle Toledo (b) (4)	21 Oct 2020 14:47:49

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:18:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '07 Oct 2020'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:47:49

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:18:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '0'	Andryelle Toledo (b) (4)	21 Oct 2020 14:47:49

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '97'	Andryelle Toledo (b) (4)	21 Oct 2020 14:47:49

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User entered '%'	System	21 Oct 2020 14:47:49

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:18:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '96.3' F	Andryelle Toledo (b) (4)	21 Oct 2020 14:47:49

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:18:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:47:49

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:18:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:47:49

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:18:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:47:49

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:18:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:47:49

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:18:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:47:49

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:18:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:47:49

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:18:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:47:49

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:18:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:47:49

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:47:49

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:47:49

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:18:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:47:49

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:18:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:47:49

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:18:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:47:49

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:18:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:47:49

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:18:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:47:49

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:18:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:47:49

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:18:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Day 10 (Day 10)'	(b) (4) Andryelle Toledo (b) (4)	21 Oct 2020 14:51:20

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:18:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '08 Oct 2020'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:51:20

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:18:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '0'	Andryelle Toledo (b) (4)	21 Oct 2020 14:51:20

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '97'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:51:20

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User entered '%'	System	21 Oct 2020 14:51:20

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:18:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '98.6' F	Andryelle Toledo (b) (4)	21 Oct 2020 14:51:20

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:18:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:51:20

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:18:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:51:20

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:18:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:51:20

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:18:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:51:20

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:18:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:51:20

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:18:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:51:20

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:18:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:51:20

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:18:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:51:20

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:51:20

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:51:20

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:18:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:51:20

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:18:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:51:20

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:18:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:51:20

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:18:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:51:20

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:18:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:51:20

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:18:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:51:20

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:18:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Day 11 (Day 11)'	(b) (4) Andryelle Toledo (b) (4)	21 Oct 2020 14:52:39

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:18:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '09 Oct 2020'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:52:39

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:18:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '0'	Andryelle Toledo (b) (4)	21 Oct 2020 14:52:39

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '95'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:52:39

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User entered '%'	System	21 Oct 2020 14:52:39

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:18:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '98.5' F	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:52:39

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:18:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:52:39

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:18:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:52:39

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:18:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:52:39

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:18:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:52:39

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:18:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:52:39

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:18:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:52:39

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:18:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:52:39

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:18:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:52:39

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:52:39

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:52:39

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:18:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:52:39

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:18:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:52:39

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:18:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:52:39

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:18:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:52:39

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:18:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:52:39

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:18:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:52:39

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:18:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Day 12 (Day 12)'	(b) (4) Andryelle Toledo (b) (4)	21 Oct 2020 14:53:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:18:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '10 Oct 2020'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:53:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:18:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '0'	Andryelle Toledo (b) (4)	21 Oct 2020 14:53:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '97'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:53:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User entered '%'	System	21 Oct 2020 14:53:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:18:29

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '97.5' F	Andryelle Toledo (b) (4)	21 Oct 2020 14:53:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:18:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:53:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:18:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:53:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:18:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:53:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:18:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:53:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:18:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:53:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:18:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:53:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:18:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:53:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:18:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:53:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:53:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:53:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:18:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:53:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:18:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:53:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:18:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:53:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:18:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:53:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:18:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:53:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:18:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:53:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:18:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Day 13 (Day 13)' reason for change:	(b) (4)	
Data Entry Error	Andryelle Toledo (b) (4)	21 Oct 2020 14:55:07
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:53:52
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:18:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Oct 2020 14:55:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 14:55:07
User entered '11 Oct 2020' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	21 Oct 2020 14:55:07
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	21 Oct 2020 14:53:52
	Andryelle Toledo (b) (4)	21 Oct 2020 14:53:52
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:18:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '0'	Andryelle Toledo (b) (4)	21 Oct 2020 14:53:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '95' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:55:07
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:53:52
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
User entered '%'	System	21 Oct 2020 14:55:07
User entered empty.	System	21 Oct 2020 14:53:52

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:18:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '97.9' F reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:55:07
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:53:52
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:18:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 14:55:07
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 14:53:52
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:18:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 14:55:07
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 14:53:52
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:18:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 14:55:07
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 14:53:52
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:18:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 14:55:07
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 14:53:52
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:18:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:55:07
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:53:52
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:18:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 14:55:07
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 14:53:52
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:18:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 14:55:07
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 14:53:52
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:18:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 14:55:07
	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:53:52
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 14:55:07
	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:53:52
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:55:07
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:53:52
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:18:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:55:07
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:53:52
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:18:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 14:55:07
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 14:53:52
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:18:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 14:55:07
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 14:53:52
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:18:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 14:55:07
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 14:53:52
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:18:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 14:55:07
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 14:53:52
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:18:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:50:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 14:55:07
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 14:53:52
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:18:29

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:28
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:51:11
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, sample dated 01OCT2020 is present in PPD central lab, please review the preclaus and update the sample details to correct subject ID and visit in PPD portal, confirm the subject ID and visit in query response.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 07:28:52
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, sample dated 01OCT2020 is present in PPD central lab, please review the preclaus and update the sample details to correct subject ID and visit in PPD portal, confirm the subject ID and visit in query response.' answered with 'Sample D1 recorded in preclarus is Unscheduled visit collected after D1. We used the D1 lab Kit, however sample did not belong to visit 1 on 01 Oct. 2020. Samples was collected on 06 Oct.2020 per PA discretion. ' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	14 Jan 2021 01:16:09
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, sample dated 01OCT2020 is present in PPD central lab, please review the preclaus and update the sample details to correct subject ID and visit in PPD portal, confirm the subject ID and visit in query response.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 08:59:30
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01OCT2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 11:54:33

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:18:29

[Date of Visit](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01OCT2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'The visit was performed via telephone on 01 Oct. 2020. The saliva kit was shipped to subject, and it was collected on DAY 3 (03 OCT. 2020). Dates are correct. I have the lab results, and confirmation in chart.' (Site from DM).	Andryelle Toledo (b) (4)	07 Dec 2020 23:47:34
User closed query 'Per GCL Reconciliation requery: Swab: Thank you for your response. Per response, "This test was collected during an unscheduled visit on 02OCT2020, Illness day" & per PPD portal, it indicates swab sample was collected at illness visit day 1 on 06-OCT-2020, kindly consider updating EDC if swab sample was collected on 02-OCT-2020 & 06-OCT-2020 under appropriate Covid-19 assessment eCRF, else clarify.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 09:35:10
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01OCT2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 04:05:01

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:18:29

[Date of Visit](#)

Audit	User	Time (GMT)
Query 'Per GCL Reconciliation requery: Swab: Thank you for your response. Per response, "This test was collected during an unscheduled visit on 02OCT2020, Illness day" & per PPD portal, it indicates swab sample was collected at illness visit day 1 on 06-OCT-2020, kindly consider updating EDC if swab sample was collected on 02-OCT-2020 & 06-OCT-2020 under appropriate Covid-19 assessment eCRF, else clarify.' answered with 'This was one of the first Illness visits we made. The information provided is correct. The D1 visit was carried out by telephone and the saliva kit sent by post to the subject on the dates provided. The PA decided to perform an unschedule nasal swab when collecting the saliva, as the subject was apparently ill. Thus being considered an unschedule visit. However, she used the D1 illness kit to perform the swab. And I carried out the reconciliation with the GSS for this visit.' (Site from DM).	Andryelle Toledo (b) (4)	02 Dec 2020 15:37:47
User opened query 'Per GCL Reconciliation requery: Swab: Thank you for your response. Per response, "This test was collected during an unscheduled visit on 02OCT2020, Illness day" & per PPD portal, it indicates swab sample was collected at illness visit day 1 on 06-OCT-2020, kindly consider updating EDC if swab sample was collected on 02-OCT-2020 & 06-OCT-2020 under appropriate Covid-19 assessment eCRF, else clarify.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 10:49:06
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 06OCT2020 is reported under Illness Visit Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample been collected under COVID Diagnostic Test then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 10:49:06
Comment added 'Please disregard all of my comments above. The saliva sample collected on 03OCT2020 was associated with illness visit on day 01OCT2020. We performed an unscheduled nasal swab on 06OCT2020.'	Leslie Iverson (b) (4)	11 Nov 2020 22:16:30
DataPoint Un-verified.	Leslie Iverson (b) (4)	11 Nov 2020 22:13:07

PRODUCTION RELEASE (v12.003
EAB) (1725)

2587 of 4365

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:18:29

[Date of Visit](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020' reason for change: Data Entry Error	Leslie Iverson (b) (4)	11 Nov 2020 22:13:07
Comment added 'Please disregard comment done at 14:31:36 which was in error. This diagnostic test was done by outside testing facility ordered by her PCP.'	Leslie Iverson (b) (4)	11 Nov 2020 21:59:50
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 06OCT2020 is reported under Illness Visit Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample been collected under COVID Diagnostic Test then update the details under appropriate visit. Else clarify, thank you.' answered with 'This test was collected during an unscheduled visit on 02OCT2020. Illness day ' (Site from DM).	Leslie Iverson (b) (4)	11 Nov 2020 21:31:36
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 06OCT2020 is reported under Illness Visit Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample been collected under COVID Diagnostic Test then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:14:36
User entered '02 Oct 2020'	Andryelle Toledo (b) (4)	21 Oct 2020 14:56:30

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:18:29

[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 21:53:28
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:14:36
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:56:30

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:18:29

[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 21:53:28
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:14:36
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:56:30

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:18:29

Date of Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:28
User closed query 'Per GCL Reconciliation: Nasopharyngeal Swab: PPD Central Labs has a Swab sample (Accession No: 1F638530668) with a date of 06-Oct-2020 for this Illness Visit. Please review if it was Swab or Saliva that was collected and the collection date. Kindly make updates in EDC and Preclarus as appropriate so that we can reconcile data with PPD central labs/Preclarus reports. Else, clarify. Thank you.	(b) (4), (b) (6)	09 Apr 2021 07:41:42
' (Site from DM). Query 'Per GCL Reconciliation: Nasopharyngeal Swab: PPD Central Labs has a Swab sample (Accession No: 1F638530668) with a date of 06-Oct-2020 for this Illness Visit. Please review if it was Swab or Saliva that was collected and the collection date. Kindly make updates in EDC and Preclarus as appropriate so that we can reconcile data with PPD central labs/Preclarus reports. Else, clarify. Thank you.	Andryelle Toledo (b) (4) (b) (4)	06 Apr 2021 16:46:53
' answered with 'Confirm collection of D3 saliva on 03 Oct 2020 and D5 on 06 Oct. 2020. because of that the date is correct. ' (Site from DM). User opened query 'Per GCL Reconciliation: Nasopharyngeal Swab: PPD Central Labs has a Swab sample (Accession No: 1F638530668) with a date of 06-Oct-2020 for this Illness Visit. Please review if it was Swab or Saliva that was collected and the collection date. Kindly make updates in EDC and Preclarus as appropriate so that we can reconcile data with PPD central labs/Preclarus reports. Else, clarify. Thank you.	(b) (4), (b) (6)	06 Apr 2021 15:46:24
' (Site from DM). User signature succeeded.	Michael Adams (b) (4) (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:14:36

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:18:29

[Date of Test](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:56:30

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:18:29

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:28
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:14:36
User entered 'Saliva Test (Saliva Test)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:56:30

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:18:29

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:28
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:14:36
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:56:30

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:18:29

[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 21:53:28
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:14:36
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:56:30

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:18:29

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:28
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:14:36
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:56:30

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:18:29

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:28
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Kindly fill out the next page of this visit "Generate Next COVID-19 Assessment"' (Site from CRA).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 20:05:32
Query 'Kindly fill out the next page of this visit "Generate Next COVID-19 Assessment"' answered with 'Subject did not tested outside.' (Site from CRA).	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 23:38:11
User opened query 'Kindly fill out the next page of this visit "Generate Next COVID-19 Assessment"' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 19:15:27
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:14:36
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:56:30

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:18:29

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:28
User entered '0'	System	21 Oct 2020 14:56:30

US3892032

Folder: Covid-19 Assessment 01 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 10:18:29

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:53:45
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 20:05:41
User entered 'No (N)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	19 Nov 2020 23:38:25
User entered 'Yes (Y)'	Rachel Law (b) (4)	16 Nov 2020 22:49:53

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:18:29

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:24
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:44
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '12 Jan 2021'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	13 Jan 2021 18:00:46

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:18:29

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:24
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:44
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '11:15'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	13 Jan 2021 18:00:46

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:18:29

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:24
User entered '12 Jan 2021 11:15'	System	13 Jan 2021 18:00:46

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:18:29

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:24
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:44
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Safety Call (Safety Call)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	13 Jan 2021 18:00:46

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:18:29

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:24
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:44
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:00:46

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Day 1 (Day 1)'	(b) (4) Andryelle Toledo (b) (4)	13 Jan 2021 18:02:21

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '11 Jan 2021'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	13 Jan 2021 18:02:21

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '0'	Andryelle Toledo (b) (4)	13 Jan 2021 18:02:21

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	13 Jan 2021 18:02:21

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
User entered empty.	System	13 Jan 2021 18:02:21

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	13 Jan 2021 18:02:21

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:02:21

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	13 Jan 2021 18:02:21

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:02:21

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	13 Jan 2021 18:02:21

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Severe (Severe)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:02:21

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	13 Jan 2021 18:02:21

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	13 Jan 2021 18:02:21

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Severe (Severe)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:02:21

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	13 Jan 2021 18:02:21

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	13 Jan 2021 18:02:21

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Severe (Severe)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:02:21

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:02:21

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:02:21

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:02:21

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:02:21

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	13 Jan 2021 18:02:21

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Day 2 (Day 2)'	(b) (4) Andryelle Toledo (b) (4)	13 Jan 2021 18:04:26

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '12 Jan 2021'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	13 Jan 2021 18:04:26

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '0'	Andryelle Toledo (b) (4)	13 Jan 2021 18:04:26

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '95'	Andryelle Toledo (b) (4)	13 Jan 2021 18:04:26

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
User entered '%'	System	13 Jan 2021 18:04:26

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '97.3' F	Andryelle Toledo (b) (4)	13 Jan 2021 18:04:26

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:04:26

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:04:26

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:04:26

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	13 Jan 2021 18:04:26

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Severe (Severe)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:04:26

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:04:26

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:04:26

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Severe (Severe)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:04:26

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:04:26

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:04:26

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Severe (Severe)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:04:26

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:04:26

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:04:26

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:04:26

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:04:26

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:04:26

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Day 3 (Day 3)'	(b) (4) Andryelle Toledo (b) (4)	13 Jan 2021 18:06:33

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '13 Jan 2021'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	13 Jan 2021 18:06:33

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '0'	Andryelle Toledo (b) (4)	13 Jan 2021 18:06:33

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '92'	Andryelle Toledo (b) (4)	13 Jan 2021 18:06:33

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
User entered '%'	System	13 Jan 2021 18:06:33

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '98.9' F	Andryelle Toledo (b) (4)	13 Jan 2021 18:06:33

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:06:33

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Severe (Severe)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:06:33

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:06:33

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:06:33

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Severe (Severe)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:06:33

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	13 Jan 2021 18:06:33

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Severe (Severe)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:06:33

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:06:33

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:06:33

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Severe (Severe)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:06:33

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:06:33

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:06:33

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:06:33

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:06:33

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:06:33

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:06:33

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Day 4 (Day 4)'	Leslie Iverson (b) (4)	14 Jan 2021 23:12:35

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '14 Jan 2021'	Leslie Iverson (b) (4)	14 Jan 2021 23:12:35

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '0'	Leslie Iverson (b) (4)	14 Jan 2021 23:12:35

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '92'	Leslie Iverson (b) (4)	14 Jan 2021 23:12:35

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
User entered '%'	System	14 Jan 2021 23:12:35

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '98.1' F	Leslie Iverson (b) (4)	14 Jan 2021 23:12:35

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:30:07
DataPoint Un-verified.	(b) (4), (b) (6)	09 Mar 2021 15:10:04
User closed query 'There is no data point marked in source for this, kindly note where this is noted, or update EDC accordingly. Thank you.' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 15:09:59
Comment added 'Sorry, on additional covid tracking log 14 Jan. 2021'.	Andryelle Toledo (b) (4)	03 Mar 2021 17:54:17
Query 'There is no data point marked in source for this, kindly note where this is noted, or update EDC accordingly. Thank you.' answered with 'Sorry, there is on day 3 Telemedicine - 15 Jan. 2021. Data reported correctly' (Site from CRA).	(b) (4)	
User opened query 'There is no data point marked in source for this, kindly note where this is noted, or update EDC accordingly. Thank you.' (Site from CRA).	Andryelle Toledo (b) (4)	03 Mar 2021 17:53:20
	(b) (4)	
User opened query 'There is no data point marked in source for this, kindly note where this is noted, or update EDC accordingly. Thank you.' (Site from CRA).	(b) (4), (b) (6)	02 Mar 2021 21:58:41
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Severe (Severe)'	(b) (4)	
	Leslie Iverson (b) (4)	14 Jan 2021 23:12:35
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Severe (Severe)'	Leslie Iverson (b) (4)	14 Jan 2021 23:12:35

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Leslie Iverson (b) (4)	14 Jan 2021 23:12:35

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Leslie Iverson (b) (4)	14 Jan 2021 23:12:35

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Severe (Severe)'	Leslie Iverson (b) (4)	14 Jan 2021 23:12:35

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Leslie Iverson (b) (4)	14 Jan 2021 23:12:35

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Severe (Severe)'	Leslie Iverson (b) (4)	14 Jan 2021 23:12:35

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Severe (Severe)'	Leslie Iverson (b) (4)	14 Jan 2021 23:12:35

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Leslie Iverson (b) (4)	14 Jan 2021 23:12:35

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Leslie Iverson (b) (4)	14 Jan 2021 23:12:35

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Leslie Iverson (b) (4)	14 Jan 2021 23:12:35

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	Leslie Iverson (b) (4)	14 Jan 2021 23:12:35

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Severe (Severe)'	Leslie Iverson (b) (4)	14 Jan 2021 23:12:35

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Leslie Iverson (b) (4)	14 Jan 2021 23:12:35

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Leslie Iverson (b) (4)	14 Jan 2021 23:12:35

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Leslie Iverson (b) (4)	14 Jan 2021 23:12:35

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Day 5 (Day 5)'	(b) (4) Leslie Iverson (b) (4)	15 Jan 2021 22:42:08

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '15 Jan 2021'	(b) (4) Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 22:42:08

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '0'	Leslie Iverson (b) (4)	15 Jan 2021 22:42:08

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '93'	Leslie Iverson (b) (4)	15 Jan 2021 22:42:08

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
User entered '%'	System	15 Jan 2021 22:42:08

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '97.1' F	Leslie Iverson (b) (4)	15 Jan 2021 22:42:08

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Severe (Severe)'	Leslie Iverson (b) (4)	15 Jan 2021 22:42:08

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	Leslie Iverson (b) (4)	15 Jan 2021 22:42:08

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Leslie Iverson (b) (4)	15 Jan 2021 22:42:08

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Leslie Iverson (b) (4)	15 Jan 2021 22:42:08

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Severe (Severe)'	Leslie Iverson (b) (4)	15 Jan 2021 22:42:08

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Severe (Severe)'	Leslie Iverson (b) (4)	15 Jan 2021 22:42:08

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Severe (Severe)'	Leslie Iverson (b) (4)	15 Jan 2021 22:42:08

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Leslie Iverson (b) (4)	15 Jan 2021 22:42:08

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Leslie Iverson (b) (4)	15 Jan 2021 22:42:08

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Leslie Iverson (b) (4)	15 Jan 2021 22:42:08

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Leslie Iverson (b) (4)	15 Jan 2021 22:42:08

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:30:07
User closed query 'Per source, this appears to be noted as 'mild' kindly confirm if EDC should be updated and update accordingly. Thank you.' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 15:10:20
Query 'Per source, this appears to be noted as 'mild' kindly confirm if EDC should be updated and update accordingly. Thank you.' answered with 'update' (Site from CRA).	Andryelle Toledo (b) (4)	03 Mar 2021 17:58:24
DataPoint Un-verified.	(b) (4)	03 Mar 2021 17:58:18
Signature has been broken.	Andryelle Toledo (b) (4)	03 Mar 2021 17:58:18
User entered 'Mild (Mild)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	03 Mar 2021 17:58:18
User opened query 'Per source, this appears to be noted as 'mild' kindly confirm if EDC should be updated and update accordingly. Thank you.' (Site from CRA).	(b) (4), (b) (6)	02 Mar 2021 22:00:47
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Leslie Iverson (b) (4)	15 Jan 2021 22:42:08

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Leslie Iverson (b) (4)	15 Jan 2021 22:42:08

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	Leslie Iverson (b) (4)	15 Jan 2021 22:42:08

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Leslie Iverson (b) (4)	15 Jan 2021 22:42:08

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:18:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:36
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:52:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Leslie Iverson (b) (4)	15 Jan 2021 22:42:08

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:18:29

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:55:20
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:02:42
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '13 Jan 2021'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	13 Jan 2021 18:02:49

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:18:29

[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 21:55:20
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:02:42
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:02:49

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:18:29

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 21:55:20
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:02:42
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Jan 2021 22:32:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Jan 2021 22:32:33
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	21 Jan 2021 22:32:33
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 18:02:49
User entered empty.	Andryelle Toledo (b) (4)	13 Jan 2021 18:02:49
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:18:29

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:55:20
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:02:42
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '13 Jan 2021'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	13 Jan 2021 18:02:49

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:18:29

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:55:20
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:02:42
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Andryelle Toledo (b) (4)	13 Jan 2021 18:02:49

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:18:29

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:55:20
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:02:42
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	13 Jan 2021 18:02:49

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:18:29

[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 21:55:20
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:02:42
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'No (N)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:02:49

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:18:29

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:55:20
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:02:42
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	13 Jan 2021 18:02:49

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:18:29

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:55:20
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:02:42
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	13 Jan 2021 18:02:49

US3892032

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:18:29

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:55:20
User entered '0'	System	21 Jan 2021 22:32:33

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:18:29

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:02
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:07:30
User entered '16 Nov 2020'	Andryelle Toledo (b) (4) (b) (4)	18 Nov 2020 00:40:29

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:18:29

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:02
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:07:30
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 11:04:15
Query 'Data is required. Please complete.' answered with 'time is unk' (Site from System).	Andryelle Toledo (b) (4)	18 Nov 2020 00:40:53
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Nov 2020 00:40:29
User entered empty.	System	18 Nov 2020 00:40:29
	Andryelle Toledo (b) (4)	18 Nov 2020 00:40:29
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:18:29

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:02
User entered empty.	System	18 Nov 2020 00:40:29

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:18:29

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:02
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:07:30
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Andryelle Toledo (b) (4) (b) (4)	18 Nov 2020 00:40:29

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:18:29

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:02
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:07:30
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	18 Nov 2020 00:40:29

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Day 1 (Day 1)'	(b) (4) Andryelle Toledo (b) (4)	18 Nov 2020 00:42:55

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '16 Nov 2020'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	18 Nov 2020 00:42:55

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '0'	Andryelle Toledo (b) (4)	18 Nov 2020 00:42:55

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '93'	Andryelle Toledo (b) (4)	18 Nov 2020 00:42:55

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
User entered '%'	System	18 Nov 2020 00:42:55

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '99.0' F	Andryelle Toledo (b) (4)	18 Nov 2020 00:42:55

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Andryelle Toledo (b) (4)	18 Nov 2020 00:42:55

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	Andryelle Toledo (b) (4)	18 Nov 2020 00:42:55

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Andryelle Toledo (b) (4)	18 Nov 2020 00:42:55

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	18 Nov 2020 00:42:55

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Andryelle Toledo (b) (4)	18 Nov 2020 00:42:55

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Andryelle Toledo (b) (4)	18 Nov 2020 00:42:55

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Andryelle Toledo (b) (4)	18 Nov 2020 00:42:55

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Severe (Severe)'	Andryelle Toledo (b) (4)	18 Nov 2020 00:42:55

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	18 Nov 2020 00:42:55

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	18 Nov 2020 00:42:55

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Andryelle Toledo (b) (4)	18 Nov 2020 00:42:55

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	18 Nov 2020 00:42:55

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Andryelle Toledo (b) (4)	18 Nov 2020 00:42:55

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	18 Nov 2020 00:42:55

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	18 Nov 2020 00:42:55

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:18:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	18 Nov 2020 00:42:55

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Day 2 (Day 2)'	(b) (4) Andryelle Toledo (b) (4)	18 Nov 2020 00:44:52

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '17 Nov 2020'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	18 Nov 2020 00:44:52

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '0'	Andryelle Toledo (b) (4)	18 Nov 2020 00:44:52

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '96' reason for change: New Information	(b) (4)	
	Leslie Iverson (b) (4)	18 Nov 2020 18:25:56
	(b) (4)	
User entered missing code ND - Not Done.	Andryelle Toledo (b) (4)	18 Nov 2020 00:44:52
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
User entered '%'	System	18 Nov 2020 00:44:52

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '97.4' F reason for change: New Information	(b) (4) Leslie Iverson (b) (4)	18 Nov 2020 18:25:56
User entered missing code ND - Not Done.	(b) (4) Andryelle Toledo (b) (4)	18 Nov 2020 00:44:52

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	Andryelle Toledo (b) (4)	18 Nov 2020 00:44:52

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	18 Nov 2020 00:44:52

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	18 Nov 2020 00:44:52

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	18 Nov 2020 00:44:52

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	18 Nov 2020 00:44:52

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	18 Nov 2020 00:44:52

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	18 Nov 2020 00:44:52

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Andryelle Toledo (b) (4)	18 Nov 2020 00:44:52

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	18 Nov 2020 00:44:52

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	18 Nov 2020 00:44:52

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	Andryelle Toledo (b) (4)	18 Nov 2020 00:44:52

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	18 Nov 2020 00:44:52

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	18 Nov 2020 00:44:52

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	18 Nov 2020 00:44:52

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	18 Nov 2020 00:44:52

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:18:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Andryelle Toledo (b) (4)	18 Nov 2020 00:44:52

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Day 3 (Day 3)'	(b) (4) Leslie Iverson (b) (4)	19 Nov 2020 00:30:17

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '18 Nov 2020'	Leslie Iverson (b) (4)	19 Nov 2020 00:30:17

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '0'	Leslie Iverson (b) (4)	19 Nov 2020 00:30:17

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '94' reason for change: Data Entry Error	(b) (4)	
	Leslie Iverson (b) (4)	19 Nov 2020 00:33:28
User entered empty.	(b) (4)	
	Leslie Iverson (b) (4)	19 Nov 2020 00:30:17
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
User entered '%'	System	19 Nov 2020 00:33:28
User entered empty.	System	19 Nov 2020 00:30:17

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	19 Nov 2020 00:33:34
User entered '98.6' F reason for change: Data Entry Error	Leslie Iverson (b) (4)	19 Nov 2020 00:33:34
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	19 Nov 2020 00:33:28
User entered '98.6' (non-conformant).	System	19 Nov 2020 00:33:28
User entered empty.	Leslie Iverson (b) (4)	19 Nov 2020 00:30:17
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Leslie Iverson (b) (4)	19 Nov 2020 00:30:17

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	Leslie Iverson (b) (4)	19 Nov 2020 00:30:17

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Leslie Iverson (b) (4)	19 Nov 2020 00:30:17

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Leslie Iverson (b) (4)	19 Nov 2020 00:30:17

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Leslie Iverson (b) (4)	19 Nov 2020 00:30:17

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Leslie Iverson (b) (4)	19 Nov 2020 00:30:17

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Leslie Iverson (b) (4)	19 Nov 2020 00:30:17

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Leslie Iverson (b) (4)	19 Nov 2020 00:30:17

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Leslie Iverson (b) (4)	19 Nov 2020 00:30:17

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Leslie Iverson (b) (4)	19 Nov 2020 00:30:17

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Leslie Iverson (b) (4)	19 Nov 2020 00:30:17

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	Leslie Iverson (b) (4)	19 Nov 2020 00:30:17

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Leslie Iverson (b) (4)	19 Nov 2020 00:30:17

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Leslie Iverson (b) (4)	19 Nov 2020 00:30:17

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Leslie Iverson (b) (4)	19 Nov 2020 00:30:17

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:18:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Leslie Iverson (b) (4)	19 Nov 2020 00:30:17

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Day 4 (Day 4)'	(b) (4) Leslie Iverson (b) (4)	19 Nov 2020 22:04:45

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Nov 2020 22:11:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 22:11:59
User entered '19 Nov 2020' reason for change: Data Entry Error	Leslie Iverson (b) (4)	19 Nov 2020 22:11:59
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Nov 2020 22:04:45
User entered empty.	System	19 Nov 2020 22:04:45
	Leslie Iverson (b) (4)	19 Nov 2020 22:04:45
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '0'	Leslie Iverson (b) (4)	19 Nov 2020 22:04:45

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '97' reason for change: Data Entry Error	(b) (4)	
	Leslie Iverson (b) (4)	19 Nov 2020 22:11:59
User entered empty.	(b) (4)	
	Leslie Iverson (b) (4)	19 Nov 2020 22:04:45
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
User entered '%'	System	19 Nov 2020 22:11:59
User entered empty.	System	19 Nov 2020 22:04:45

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '96.8' F reason for change: Data Entry Error	(b) (4)	19 Nov 2020 22:11:59
User entered empty.	Leslie Iverson (b) (4)	19 Nov 2020 22:04:45
	(b) (4)	

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	Leslie Iverson (b) (4)	19 Nov 2020 22:04:45

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	Leslie Iverson (b) (4)	19 Nov 2020 22:04:45

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	Leslie Iverson (b) (4)	19 Nov 2020 22:04:45

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Leslie Iverson (b) (4)	19 Nov 2020 22:04:45

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Moderate (Moderate)'	Leslie Iverson (b) (4)	19 Nov 2020 22:04:45

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Leslie Iverson (b) (4)	19 Nov 2020 22:04:45

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Leslie Iverson (b) (4)	19 Nov 2020 22:04:45

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Leslie Iverson (b) (4)	19 Nov 2020 22:04:45

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Leslie Iverson (b) (4)	19 Nov 2020 22:04:45

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Leslie Iverson (b) (4)	19 Nov 2020 22:04:45

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Mild (Mild)'	Leslie Iverson (b) (4)	19 Nov 2020 22:04:45

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Leslie Iverson (b) (4)	19 Nov 2020 22:04:45

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Leslie Iverson (b) (4)	19 Nov 2020 22:04:45

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Leslie Iverson (b) (4)	19 Nov 2020 22:04:45

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Leslie Iverson (b) (4)	19 Nov 2020 22:04:45

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:18:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:29:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'None (None)'	Leslie Iverson (b) (4)	19 Nov 2020 22:04:45

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:18:29

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:51:39
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '16 Nov 2020'	Andryelle Toledo (b) (4)	18 Nov 2020 00:43:14

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:18:29

[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 21:54:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:51:39
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	18 Nov 2020 00:43:14

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:18:29

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 21:54:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:51:39
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'PER CDM: Re-Query: Response reported as "waiting for results". However, request you to please keep the query open until the site receive the data and record as appropriate. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 01:19:43
Query 'PER CDM: Re-Query: Response reported as "waiting for results". However, request you to please keep the query open until the site receive the data and record as appropriate. Thank you. ' answered with 'update' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	20 Nov 2020 19:20:25
User entered 'No (N)' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	20 Nov 2020 19:20:16
User opened query 'PER CDM: Re-Query: Response reported as "waiting for results". However, request you to please keep the query open until the site receive the data and record as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 11:09:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 11:09:41
Query 'Data is required. Please complete.' answered with 'waiting for results' (Site from System).	Andryelle Toledo (b) (4) (b) (4)	18 Nov 2020 00:43:24
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 00:43:14
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	18 Nov 2020 00:43:14

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:18:29

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:51:39
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '16 Nov 2020'	Andryelle Toledo (b) (4)	18 Nov 2020 00:43:14

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:18:29

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:51:39
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Andryelle Toledo (b) (4)	18 Nov 2020 00:43:14

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:18:29

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:51:39
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	18 Nov 2020 00:43:14

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:18:29

[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 21:54:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:51:39
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'No (N)'	Andryelle Toledo (b) (4)	18 Nov 2020 00:43:14

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:18:29

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:51:39
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	18 Nov 2020 00:43:14

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:18:29

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:51:39
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	18 Nov 2020 00:43:14

US3892032

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:18:29

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:54:16
User entered '0'	System	20 Nov 2020 19:20:16

US3892032

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 10:18:29

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per Lab Recon: Saliva: Sample dated 3Oct2020 is reported under Illness Visit Day 3 in EDC, however GCL same is reported for Day 21 in PPD central lab. Please confirm the correct visit in query response and update the visit mismatch in EDC or Preclarus as appropriate, Thank you. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 07:36:29
Query 'Per Lab Recon: Saliva: Sample dated 3Oct2020 is reported under Illness Visit Day 3 in EDC, however GCL same is reported for Day 21 in PPD central lab. Please confirm the correct visit in query response and update the visit mismatch in EDC or Preclarus as appropriate, Thank you. ' answered with 'Subject collected the saliva sample under the wrong DATE tube. I reconciliated that with GSS. ' (Site from DM).	Andryelle Toledo (b) (4)	23 Mar 2021 14:58:05
User opened query 'Per Lab Recon: Saliva: Sample dated 3Oct2020 is reported under Illness Visit Day 3 in EDC, however GCL same is reported for Day 21 in PPD central lab. Please confirm the correct visit in query response and update the visit mismatch in EDC or Preclarus as appropriate, Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 09:29:51
User accepted default value 'Day 3 (Day 3)'	Rachel Law (b) (4)	16 Nov 2020 22:58:12

US3892032

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 10:18:29

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:04:20
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Yes (Y)'	Rachel Law (b) (4)	16 Nov 2020 22:58:12

US3892032

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 10:18:29

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:04:20
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '03 Oct 2020' reason for change: Data Entry Error	(b) (4)	23 Nov 2020 17:19:14
User entered '3 Oct 2020'	Andryelle Toledo (b) (4)	23 Nov 2020 17:19:14
	(b) (4)	
	Rachel Law (b) (4)	16 Nov 2020 22:58:12
	(b) (4)	

US3892032

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 10:18:29

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Rachel Law (b) (4) (b) (4)	16 Nov 2020 22:58:12

US3892032

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 10:18:29

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:04:20
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Yes (Y)'	Rachel Law (b) (4)	16 Nov 2020 22:58:12

US3892032

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 10:18:29

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:04:20
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number in query response for tracking purpose.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 07:25:24
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number in query response for tracking purpose.' answered with 'accession number is 1F650686170' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 22:37:00
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 09:07:13
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the tracking details in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 09:07:13
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the tracking details in query response for tracking purpose.' answered with 'Tracking:9255.6658.1025' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	14 Jan 2021 01:30:37
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the tracking details in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 06:24:28
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 05OCT2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 11:53:35

US3892032

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 10:18:29

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 05OCT2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'Please, review queries. I have results and confirmations inside the chart. Thank you' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	07 Dec 2020 23:48:43
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 05OCT2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4)	07 Dec 2020 11:12:32
User entered '05 Oct 2020' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	23 Nov 2020 17:19:14
User entered '5 Oct 2020'	Rachel Law (b) (4) (b) (4)	16 Nov 2020 22:58:12

US3892032

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 10:18:29

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Rachel Law (b) (4) (b) (4)	16 Nov 2020 22:58:12

US3892032

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 10:18:29

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:04:20
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'NA (COVID-19 Negative) (NA)'	Rachel Law (b) (4)	16 Nov 2020 22:58:12

US3892032

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 10:18:29

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:04:20
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Rachel Law (b) (4)	16 Nov 2020 22:58:12

US3892032

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 10:18:29

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Rachel Law (b) (4) (b) (4)	16 Nov 2020 22:58:12

US3892032

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 10:18:29

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:04:20
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'NA (COVID-19 Negative) (NA)'	Rachel Law (b) (4)	16 Nov 2020 22:58:12

US3892032

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 10:18:29

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:04:20
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Rachel Law (b) (4)	16 Nov 2020 22:58:12

US3892032

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 10:18:29

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Rachel Law (b) (4) (b) (4)	16 Nov 2020 22:58:12

US3892032

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 10:18:29

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:04:20
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'NA (COVID-19 Negative) (NA)'	Rachel Law (b) (4)	16 Nov 2020 22:58:12

US3892032

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 10:18:29

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:04:20
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Rachel Law (b) (4)	16 Nov 2020 22:58:12

US3892032

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 10:18:29

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Rachel Law (b) (4) (b) (4)	16 Nov 2020 22:58:12

US3892032

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 10:18:29

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:04:20
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'NA (COVID-19 Negative) (NA)'	Rachel Law (b) (4)	16 Nov 2020 22:58:12

US3892032

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 10:18:29

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:04:20
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Rachel Law (b) (4)	16 Nov 2020 22:58:12

US3892032

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 10:18:29

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Rachel Law (b) (4) (b) (4)	16 Nov 2020 22:58:12

US3892032

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 10:18:29

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:04:20
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'NA (COVID-19 Negative) (NA)'	Rachel Law (b) (4)	16 Nov 2020 22:58:12

US3892032

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 10:18:29

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:04:20
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Rachel Law (b) (4)	16 Nov 2020 22:58:12

US3892032

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 10:18:29

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Andryelle Toledo (b) (4)	23 Nov 2020 17:18:47
	(b) (4)	

US3892032

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 10:18:29

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:08:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	23 Nov 2020 17:18:47

US3892032

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 10:18:29

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:08:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '18 Nov 2020'	Andryelle Toledo (b) (4)	23 Nov 2020 17:18:47

US3892032

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 10:18:29

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Andryelle Toledo (b) (4) (b) (4)	23 Nov 2020 17:18:47

US3892032

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 10:18:29

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:08:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'NA (COVID-19 Negative) (NA)'	Andryelle Toledo (b) (4)	23 Nov 2020 17:18:47

US3892032

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 10:18:29

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:08:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	23 Nov 2020 17:18:47

US3892032

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 10:18:29

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Andryelle Toledo (b) (4)	23 Nov 2020 17:18:47
	(b) (4)	

US3892032

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 10:18:29

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:08:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'NA (COVID-19 Negative) (NA)'	Andryelle Toledo (b) (4)	23 Nov 2020 17:18:47

US3892032

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 10:18:29

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:08:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	23 Nov 2020 17:18:47

US3892032

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 10:18:29

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Andryelle Toledo (b) (4)	23 Nov 2020 17:18:47
	(b) (4)	

US3892032

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 10:18:29

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:08:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'NA (COVID-19 Negative) (NA)'	Andryelle Toledo (b) (4)	23 Nov 2020 17:18:47

US3892032

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 10:18:29

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:08:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	23 Nov 2020 17:18:47

US3892032

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 10:18:29

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Andryelle Toledo (b) (4) (b) (4)	23 Nov 2020 17:18:47

US3892032

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 10:18:29

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:08:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'NA (COVID-19 Negative) (NA)'	Andryelle Toledo (b) (4)	23 Nov 2020 17:18:47

US3892032

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 10:18:29

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:08:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	23 Nov 2020 17:18:47

US3892032

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 10:18:29

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Andryelle Toledo (b) (4) (b) (4)	23 Nov 2020 17:18:47

US3892032

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 10:18:29

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:08:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'NA (COVID-19 Negative) (NA)'	Andryelle Toledo (b) (4)	23 Nov 2020 17:18:47

US3892032

Folder: Illness Visit (2)

Form: Saliva Collection (6)

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[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:08:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	23 Nov 2020 17:18:47

US3892032

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 10:18:29

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Andryelle Toledo (b) (4) (b) (4)	23 Nov 2020 17:18:47

US3892032

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 10:18:29

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:08:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'NA (COVID-19 Negative) (NA)'	Andryelle Toledo (b) (4)	23 Nov 2020 17:18:47

US3892032

Folder: Illness Visit (2)

Form: Saliva Collection (7)

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[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:08:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	23 Nov 2020 17:18:47

US3892032

Folder: Illness Visit (3)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 10:18:29

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:57
User accepted default value 'Day 3 (Day 3)'	Andryelle Toledo (b) (4)	29 Jan 2021 22:28:48
	(b) (4)	

US3892032

Folder: Illness Visit (3)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 10:18:29

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:57
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:09:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	29 Jan 2021 22:28:48

US3892032

Folder: Illness Visit (3)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 10:18:29

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:57
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:09:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '16 Jan 2021'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	29 Jan 2021 22:28:48

US3892032

Folder: Illness Visit (3)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 10:18:29

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:57
User accepted default value 'Day 5 (Day 5)'	Andryelle Toledo (b) (4)	29 Jan 2021 22:28:48
	(b) (4)	

US3892032

Folder: Illness Visit (3)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 10:18:29

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:57
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:09:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'NA (COVID-19 Negative) (NA)'	Andryelle Toledo (b) (4)	29 Jan 2021 22:28:48

US3892032

Folder: Illness Visit (3)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 10:18:29

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:57
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:09:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	(b) (4) Andryelle Toledo (b) (4) (b) (4)	29 Jan 2021 22:28:48

US3892032

Folder: Illness Visit (3)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 10:18:29

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:57
User accepted default value 'Day 7 (Day 7)'	Andryelle Toledo (b) (4)	29 Jan 2021 22:28:48
	(b) (4)	

US3892032

Folder: Illness Visit (3)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 10:18:29

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:57
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:09:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'NA (COVID-19 Negative) (NA)'	Andryelle Toledo (b) (4)	29 Jan 2021 22:28:48

US3892032

Folder: Illness Visit (3)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 10:18:29

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:57
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:09:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	(b) (4) Andryelle Toledo (b) (4) (b) (4)	29 Jan 2021 22:28:48

US3892032

Folder: Illness Visit (3)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 10:18:29

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:57
User accepted default value 'Day 9 (Day 9)'	Andryelle Toledo (b) (4)	29 Jan 2021 22:28:48
	(b) (4)	

US3892032

Folder: Illness Visit (3)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 10:18:29

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:57
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:09:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'NA (COVID-19 Negative) (NA)'	Andryelle Toledo (b) (4)	29 Jan 2021 22:28:48

US3892032

Folder: Illness Visit (3)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 10:18:29

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:57
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:09:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	(b) (4) Andryelle Toledo (b) (4) (b) (4)	29 Jan 2021 22:28:48

US3892032

Folder: Illness Visit (3)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 10:18:29

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:57
User accepted default value 'Day 14 (Day 14)'	Andryelle Toledo (b) (4)	29 Jan 2021 22:28:48
	(b) (4)	

US3892032

Folder: Illness Visit (3)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 10:18:29

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:57
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:09:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'NA (COVID-19 Negative) (NA)'	Andryelle Toledo (b) (4)	29 Jan 2021 22:28:48

US3892032

Folder: Illness Visit (3)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 10:18:29

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:57
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:09:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	(b) (4) Andryelle Toledo (b) (4) (b) (4)	29 Jan 2021 22:28:48

US3892032

Folder: Illness Visit (3)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 10:18:29

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:57
User accepted default value 'Day 21 (Day 21)'	Andryelle Toledo (b) (4)	29 Jan 2021 22:28:48
	(b) (4)	

US3892032

Folder: Illness Visit (3)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 10:18:29

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:57
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:09:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'NA (COVID-19 Negative) (NA)'	Andryelle Toledo (b) (4)	29 Jan 2021 22:28:48

US3892032

Folder: Illness Visit (3)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 10:18:29

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:57
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:09:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	(b) (4) Andryelle Toledo (b) (4) (b) (4)	29 Jan 2021 22:28:48

US3892032

Folder: Illness Visit (3)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 10:18:29

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:57
User accepted default value 'Day 28 (Day 28)'	Andryelle Toledo (b) (4)	29 Jan 2021 22:28:48
	(b) (4)	

US3892032

Folder: Illness Visit (3)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 10:18:29

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:57
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:09:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'NA (COVID-19 Negative) (NA)'	Andryelle Toledo (b) (4)	29 Jan 2021 22:28:48

US3892032

Folder: Illness Visit (3)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 10:18:29

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:57
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:09:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	(b) (4) Andryelle Toledo (b) (4) (b) (4)	29 Jan 2021 22:28:48

US3892032

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:02:56
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:49:48
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:48:56
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Andryelle Toledo (b) (4)	23 Feb 2021 00:25:07
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Andryelle Toledo (b) (4)	23 Feb 2021 00:24:50
User entered 'No (N)'	Rachel Law (b) (4)	16 Nov 2020 22:54:08

US3892032

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:02:56
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:49:51
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:48:56
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty; reason for change Data Entry Error	(b) (4) Andryelle Toledo (b) (4)	23 Feb 2021 00:25:07
User entered '01 Oct 2020' reason for change: Data Entry Error	(b) (4) Andryelle Toledo (b) (4)	23 Feb 2021 00:24:50
User entered empty.	Rachel Law (b) (4)	16 Nov 2020 22:54:08
	(b) (4)	

US3892032

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:02:56
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:49:53
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:48:56
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	(b) (4)	23 Feb 2021 00:25:07
User opened query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	System	23 Feb 2021 00:24:50
User entered empty.	Rachel Law (b) (4)	16 Nov 2020 22:54:08
	(b) (4)	

US3892032

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	16 Nov 2020 22:54:08

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:03:04
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:49:22
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:49:04
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Response to were vital signs assessed is No, but height or weight is provided. Please correct.' (Site from System).	(b) (4)	23 Nov 2020 17:19:52
User opened query 'Response to were vital signs assessed is No, but height or weight is provided. Please correct.' (Site from System).	System	23 Nov 2020 17:19:41
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 22:54:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 22:54:35
User entered 'No (N)' reason for change: Data Entry Error	Rachel Law (b) (4)	16 Nov 2020 22:54:35
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	16 Nov 2020 22:52:33
User entered empty.	System	16 Nov 2020 22:52:33
	Rachel Law (b) (4)	16 Nov 2020 22:52:33
	(b) (4)	

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:03:04
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:49:25
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:49:04
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Rachel Law (b) (4)	16 Nov 2020 22:52:33

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:03:04
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:49:27
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:49:04
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Rachel Law (b) (4)	16 Nov 2020 22:52:33

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 22:52:33

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:03:04
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:49:29
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:49:04
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Rachel Law (b) (4)	16 Nov 2020 22:52:33

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:03:04
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:49:31
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:49:04
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Rachel Law (b) (4)	16 Nov 2020 22:52:33

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:03:04
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:49:34
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:49:04
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Rachel Law (b) (4)	16 Nov 2020 22:52:33

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:03:04
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:49:35
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:49:04
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Rachel Law (b) (4)	16 Nov 2020 22:52:33

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 22:52:33

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:03:04
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:49:37
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:49:04
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Rachel Law (b) (4)	16 Nov 2020 22:52:33

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 22:52:33

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:03:04
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:49:39
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:49:04
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Rachel Law (b) (4)	16 Nov 2020 22:52:33

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 22:52:33

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:03:04
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:49:41
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:49:04
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Rachel Law (b) (4)	16 Nov 2020 22:52:33

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 22:52:33

US3892032

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:18:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:03:14
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'No (N)'	Rachel Law (b) (4)	16 Nov 2020 22:54:43

US3892032

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:18:29

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:03:14
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Rachel Law (b) (4)	16 Nov 2020 22:54:43

US3892032

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 10:18:29

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:03:24
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'No (N)'	Rachel Law (b) (4)	16 Nov 2020 22:54:48

US3892032

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 10:18:29

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:03:24
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Rachel Law (b) (4)	16 Nov 2020 22:54:48

US3892032

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:04:54
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Yes (Y)'	Rachel Law (b) (4)	16 Nov 2020 22:58:38

US3892032

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:04:54
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '16 Nov 2020'	Rachel Law (b) (4)	16 Nov 2020 22:58:38

US3892032

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 20:28:02
User closed query 'Per source 'clinic' is checked. Kindly confirm where visit was performed and updated EDC/Source accordingly. Thank you.' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 15:13:38
Query 'Per source 'clinic' is checked. Kindly confirm where visit was performed and updated EDC/Source accordingly. Thank you.' answered with 'update' (Site from CRA).	Andryelle Toledo (b) (4)	03 Mar 2021 16:57:55
	(b) (4)	
DataPoint Un-verified.	Andryelle Toledo (b) (4)	03 Mar 2021 16:57:36
	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	03 Mar 2021 16:57:36
	(b) (4)	
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	03 Mar 2021 16:57:36
	(b) (4)	
User opened query 'Per source 'clinic' is checked. Kindly confirm where visit was performed and updated EDC/Source accordingly. Thank you.' (Site from CRA).	(b) (4), (b) (6)	02 Mar 2021 22:06:11
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:04:54
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
User entered 'Home (Home)'	Rachel Law (b) (4)	16 Nov 2020 22:58:38
	(b) (4)	

US3892032

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	16 Nov 2020 22:58:38

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:06:47
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Yes (Y)'	Rachel Law (b) (4)	16 Nov 2020 22:59:15

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:06:47
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '16 Nov 2020'	Rachel Law (b) (4)	16 Nov 2020 22:59:15

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:06:47
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '10:44'	Rachel Law (b) (4)	16 Nov 2020 22:59:15

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
User entered '16 Nov 2020 10:44'	System	16 Nov 2020 22:59:15

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:06:47
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '99.0' F	Rachel Law (b) (4)	16 Nov 2020 22:59:15

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:06:47
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Oral (Oral)'	Rachel Law (b) (4)	16 Nov 2020 22:59:15

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:06:47
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Rachel Law (b) (4)	16 Nov 2020 22:59:15

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:06:47
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '86'	Rachel Law (b) (4)	16 Nov 2020 22:59:15

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	16 Nov 2020 22:59:15

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:06:47
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Per CDM: Per CCG V2.0 page 53, Respiratory Rate >16 breaths/min is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Nov 2020 06:51:58
Query 'Per CDM: Per CCG V2.0 page 53, Respiratory Rate >16 breaths/min is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' answered with 'NCS per investigator' (Site from DM).	Leslie Iverson (b) (4) (b) (4)	25 Nov 2020 15:05:18
User opened query 'Per CDM: Per CCG V2.0 page 53, Respiratory Rate >16 breaths/min is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 03:45:06
User entered '18'	Rachel Law (b) (4) (b) (4)	16 Nov 2020 22:59:15

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	16 Nov 2020 22:59:15

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:06:47
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '107'	Rachel Law (b) (4)	16 Nov 2020 22:59:15

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Nov 2020 22:59:15

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:06:47
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '76'	Rachel Law (b) (4)	16 Nov 2020 22:59:15

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Nov 2020 22:59:15

US3892032

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:18:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:07:13
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Yes (Y)'	Rachel Law (b) (4)	16 Nov 2020 22:59:42

US3892032

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:18:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:07:13
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '16 Nov 2020'	Rachel Law (b) (4)	16 Nov 2020 22:59:42

US3892032

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 10:18:29

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:07:25
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'No (N)'	Rachel Law (b) (4)	16 Nov 2020 22:59:48

US3892032

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 10:18:29

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:07:25
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Rachel Law (b) (4)	16 Nov 2020 22:59:48

US3892032

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:10
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:09:05
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	13 Jan 2021 17:58:14

US3892032

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:10
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:09:05
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '13 Jan 2021'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	13 Jan 2021 17:58:14

US3892032

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

[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 11:17:10
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:09:05
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Clinic (Clinic)'	Andryelle Toledo (b) (4)	13 Jan 2021 17:58:14

US3892032

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:10
User entered 'SICKD1'	System	13 Jan 2021 17:58:14

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:17
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:10:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	13 Jan 2021 17:58:54

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:17
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:10:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '13 Jan 2021'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	13 Jan 2021 17:58:54

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:17
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:10:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '08:30'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	13 Jan 2021 17:58:54

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:17
User entered '13 Jan 2021 08:30'	System	13 Jan 2021 17:58:54

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:17
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:10:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '98.9' F	(b) (4) Andryelle Toledo (b) (4) (b) (4)	13 Jan 2021 17:58:54

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:17
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:10:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Oral (Oral)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	13 Jan 2021 17:58:54

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:17
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:10:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	(b) (4) Andryelle Toledo (b) (4) (b) (4)	13 Jan 2021 17:58:54

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:17
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:10:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '93'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	13 Jan 2021 17:58:54

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:17
User entered 'bpm'	System	13 Jan 2021 17:58:54

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:17
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:10:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '16'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	13 Jan 2021 17:58:54

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:17
User entered 'breaths/min'	System	13 Jan 2021 17:58:54

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:17
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:10:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '120'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	13 Jan 2021 17:58:54

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:17
User entered 'mmHg'	System	13 Jan 2021 17:58:54

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:17
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:10:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '73'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	13 Jan 2021 17:58:54

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:17
User entered 'mmHg'	System	13 Jan 2021 17:58:54

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:17

US3892032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:17

US3892032

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:18:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:23
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:11:43
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	13 Jan 2021 17:59:03

US3892032

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:18:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:23
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:11:43
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '13 Jan 2021'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	13 Jan 2021 17:59:03

US3892032

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 10:18:29

[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 11:17:30
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:09:18
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	13 Jan 2021 17:59:14

US3892032

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 10:18:29

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:30
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:09:18
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Per Lab Recon: SARS-COV2: Sample dated 13 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:26:34
Query 'Per Lab Recon: SARS-COV2: Sample dated 13 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.' answered with 'The sample was shipped, the Accession number is 1F623207450' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	29 Jan 2021 22:32:14
User opened query 'Per Lab Recon: SARS-COV2: Sample dated 13 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 13:52:12
User entered '13 Jan 2021'	Andryelle Toledo (b) (4) (b) (4)	13 Jan 2021 17:59:14

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:03:34
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'No (N)'	Rachel Law (b) (4)	16 Nov 2020 22:55:02

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:03:34
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Rachel Law (b) (4)	16 Nov 2020 22:55:02

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:03:34
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Rachel Law (b) (4)	16 Nov 2020 22:55:02

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	16 Nov 2020 22:55:02

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:03:45
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'No (N)'	Rachel Law (b) (4)	16 Nov 2020 22:55:08

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:03:45
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Rachel Law (b) (4)	16 Nov 2020 22:55:08

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:03:45
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Rachel Law (b) (4)	16 Nov 2020 22:55:08

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 22:55:08

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:03:45
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Rachel Law (b) (4)	16 Nov 2020 22:55:08

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:03:45
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Rachel Law (b) (4)	16 Nov 2020 22:55:08

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:03:45
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Rachel Law (b) (4)	16 Nov 2020 22:55:08

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:03:45
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Rachel Law (b) (4)	16 Nov 2020 22:55:08

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 22:55:08

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:03:45
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Rachel Law (b) (4)	16 Nov 2020 22:55:08

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 22:55:08

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:03:45
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Rachel Law (b) (4)	16 Nov 2020 22:55:08

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 22:55:08

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:03:45
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Rachel Law (b) (4)	16 Nov 2020 22:55:08

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 22:55:08

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:18:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:03:56
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'No (N)'	Rachel Law (b) (4)	16 Nov 2020 22:55:12

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:18:29

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:03:56
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Rachel Law (b) (4)	16 Nov 2020 22:55:12

US3892032

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 10 Jun 2021 10:18:29

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: illness visit not done but Saliva Log completed for Illness Visit 1. Thankyou.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 06:42:43
User signature succeeded.	(b) (4), (b) (6)	02 Mar 2021 22:04:08
Query 'Per GCL Lab Reconciliation: illness visit not done but Saliva Log completed for Illness Visit 1. Thankyou.' answered with 'Illness visit was performed via SAFETY CALL. I shipped the saliva samples to subject home. The sample D3 is the sample used to check if subject has or not COVID-19. The saliva log is correct completed. Review the query.' (Site from DM).	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User opened query 'Per GCL Lab Reconciliation: illness visit not done but Saliva Log completed for Illness Visit 1. Thankyou.' (Site from DM).	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Andryelle Toledo (b) (4)	23 Feb 2021 00:23:52
	(b) (4)	
	(b) (4), (b) (6)	22 Feb 2021 13:55:32
	Rachel Law (b) (4)	16 Nov 2020 22:55:34
	(b) (4)	

US3892032

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 10 Jun 2021 10:18:29

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:04:08
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Rachel Law (b) (4)	16 Nov 2020 22:55:34

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:07:43
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'No (N)'	Andryelle Toledo (b) (4)	23 Nov 2020 17:17:44

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:07:43
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	23 Nov 2020 17:17:44

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:07:43
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	23 Nov 2020 17:17:44

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	23 Nov 2020 17:17:44

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:07:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'No (N)'	Andryelle Toledo (b) (4)	23 Nov 2020 17:17:49

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:07:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	23 Nov 2020 17:17:49

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:07:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	23 Nov 2020 17:17:49

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 17:17:49

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:07:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	23 Nov 2020 17:17:49

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:07:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	23 Nov 2020 17:17:49

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:07:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	23 Nov 2020 17:17:49

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:07:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	23 Nov 2020 17:17:49

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 17:17:49

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:07:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	23 Nov 2020 17:17:49

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 17:17:49

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:07:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	23 Nov 2020 17:17:49

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 17:17:49

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:07:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	23 Nov 2020 17:17:49

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 17:17:49

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:18:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:08:01
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'No (N)'	Andryelle Toledo (b) (4)	23 Nov 2020 17:17:55

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:18:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:08:01
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	23 Nov 2020 17:17:55

US3892032

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 10 Jun 2021 10:18:29

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:08:13
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'NA (COVID-19 Negative) (NA)'	Andryelle Toledo (b) (4)	23 Nov 2020 17:18:00

US3892032

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 10 Jun 2021 10:18:29

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:08:13
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	23 Nov 2020 17:18:00

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:09:46
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'No (N)'	Andryelle Toledo (b) (4)	29 Jan 2021 22:27:00

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:09:46
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	29 Jan 2021 22:27:00

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:09:46
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	29 Jan 2021 22:27:00

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	29 Jan 2021 22:27:00

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:09:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'No (N)'	Andryelle Toledo (b) (4)	29 Jan 2021 22:27:07

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:09:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	29 Jan 2021 22:27:07

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:09:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	29 Jan 2021 22:27:07

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 22:27:07

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:09:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	29 Jan 2021 22:27:07

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:09:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	29 Jan 2021 22:27:07

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:09:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	29 Jan 2021 22:27:07

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:09:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	29 Jan 2021 22:27:07

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 22:27:07

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:09:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	29 Jan 2021 22:27:07

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 22:27:07

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:09:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	29 Jan 2021 22:27:07

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 22:27:07

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:09:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	29 Jan 2021 22:27:07

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 22:27:07

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:18:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:10:05
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'No (N)'	Andryelle Toledo (b) (4)	29 Jan 2021 22:27:14

US3892032

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:18:29

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:10:05
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	29 Jan 2021 22:27:14

US3892032

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 10 Jun 2021 10:18:29

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:10:16
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'NA (COVID-19 Negative) (NA)'	Andryelle Toledo (b) (4)	29 Jan 2021 22:27:25

US3892032

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 10 Jun 2021 10:18:29

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:10:16
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	29 Jan 2021 22:27:25

US3892032

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

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:47:31
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Feb 2021 21:47:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Feb 2021 21:47:18
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 21:47:18
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Feb 2021 21:04:29
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 21:04:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Feb 2021 21:01:11

US3892032

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

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:47:31
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '15 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 21:47:18
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 21:04:29
User entered '15 Feb 2021'	(b) (4), (b) (6)	15 Feb 2021 21:01:11

US3892032

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

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

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 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:47:31
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 21:47:18
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 21:04:29
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	15 Feb 2021 21:01:11

US3892032

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

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
User entered 'UNBLND_DECIDE'	System	15 Feb 2021 21:47:18
User entered empty.	System	15 Feb 2021 21:04:29
User entered 'UNBLND_DECIDE'	System	15 Feb 2021 21:01:11

US3892032

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

Form: Unblinding

Generated On: 10 Jun 2021 10:18:29

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:16:57
User closed query 'unable to locate IRT unblinding source in subject chart. Kindly provide. And ensure that this page is correctly filled out. Was dose #1 mRNA? Please correct EDC if indicated. Thank you.' (Site from CRA).	(b) (4), (b) (6)	02 Mar 2021 18:35:58
Query 'unable to locate IRT unblinding source in subject chart. Kindly provide. And ensure that this page is correctly filled out. Was dose #1 mRNA? Please correct EDC if indicated. Thank you.' answered with 'It is under the tab IWRS.' (Site from CRA).	Andryelle Toledo (b) (4) (b) (4)	02 Mar 2021 14:25:15
User opened query 'unable to locate IRT unblinding source in subject chart. Kindly provide. And ensure that this page is correctly filled out. Was dose #1 mRNA? Please correct EDC if indicated. Thank you.' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 22:52:21
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 22:50:57
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:50:31
User signature succeeded.	Michael Adams (b) (4) (b) (4)	23 Feb 2021 18:10:34
User entered '13 Jan 2021'	(b) (4), (b) (6)	15 Feb 2021 21:55:54

US3892032

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

Form: Unblinding

Generated On: 10 Jun 2021 10:18:29

[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 07:44:51
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:04:22

US3892032

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

Form: Unblinding

Generated On: 10 Jun 2021 10:18:29

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:16:57
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 22:50:59
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:50:31
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Feb 2021 21:55:54

US3892032

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

Form: Unblinding

Generated On: 10 Jun 2021 10:18:29

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:04:22

US3892032

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

Form: Unblinding

Generated On: 10 Jun 2021 10:18:29

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:16:57
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 22:51:00
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:50:31
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '15 Feb 2021'	(b) (4), (b) (6)	15 Feb 2021 21:55:54

US3892032

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

Form: Unblinding

Generated On: 10 Jun 2021 10:18:29

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:16:57
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 22:51:02
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:50:31
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	15 Feb 2021 21:55:54

US3892032

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

Form: Unblinding

Generated On: 10 Jun 2021 10:18:29

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:16:57
User closed query 'Kindly update to Placebo, as subject received Placebo at Part A of the Protocol, this should activate Exposure page on OL-D29 visit. Thank you. ' (Site from CRA). Query 'Kindly update to Placebo, as subject received Placebo at Part A of the Protocol, this should activate Exposure page on OL-D29 visit. Thank you. ' answered with 'UPDATE' (Site from CRA). Signature has been broken.	(b) (4), (b) (6) Andryelle Toledo (b) (4) (b) (4) Andryelle Toledo (b) (4) (b) (4) Andryelle Toledo (b) (4) (b) (4) Andryelle Toledo (b) (4)	22 Mar 2021 17:21:41 22 Mar 2021 17:08:12 22 Mar 2021 17:07:21 22 Mar 2021 17:07:21 19 Mar 2021 16:15:52
User entered 'Placebo (Placebo)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Mar 2021 22:51:04
User opened query 'Kindly update to Placebo, as subject received Placebo at Part A of the Protocol, this should activate Exposure page on OL-D29 visit. Thank you. ' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 22:50:31
DataPoint Un-verified.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 21:55:54
User signature succeeded.		
User entered 'mRNA-1273 (mRNA-1273)'		

US3892032

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

Form: Unblinding

Generated On: 10 Jun 2021 10:18:29

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:16:57
User closed query 'Kindly update to Placebo, as subject received Placebo at Part A of the Protocol, this should activate Exposure page on OL-D29 visit. Thank you. ' (Site from CRA). Query 'Kindly update to Placebo, as subject received Placebo at Part A of the Protocol, this should activate Exposure page on OL-D29 visit. Thank you. ' answered with 'Update' (Site from CRA). Signature has been broken.	(b) (4), (b) (6) Andryelle Toledo (b) (4) (b) (4) Andryelle Toledo (b) (4) (b) (4) Andryelle Toledo (b) (4) (b) (4)	22 Mar 2021 17:21:43 22 Mar 2021 17:08:19 22 Mar 2021 17:07:21 22 Mar 2021 17:07:21 19 Mar 2021 16:16:04
User entered 'Placebo (Placebo)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Mar 2021 22:51:06
User opened query 'Kindly update to Placebo, as subject received Placebo at Part A of the Protocol, this should activate Exposure page on OL-D29 visit. Thank you. ' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 22:50:31
DataPoint Un-verified.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 21:55:54
User signature succeeded.	(b) (4), (b) (6)	
User entered 'Not Administered (NA)'		

US3892032

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

Form: Unblinding

Generated On: 10 Jun 2021 10:18:29

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:16:57
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 22:51:08
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:50:31
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Feb 2021 21:55:54

US3892032

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

Form: Unblinding

Generated On: 10 Jun 2021 10:18:29

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
User entered '1'	System	22 Mar 2021 17:07:21
User entered empty.	System	15 Feb 2021 21:55:54

US3892032

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

Form: Unblinding

Generated On: 10 Jun 2021 10:18:29

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
User entered 'I'	System	15 Feb 2021 21:55:54

US3892032

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:18:29

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:52:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Kindly update EDC with the remaining data from this visit. Thank you.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:53:04
Query 'Kindly update EDC with the remaining data from this visit. Thank you.' answered with 'update' (Site from CRA).	Andryelle Toledo (b) (4) (b) (4)	18 Feb 2021 22:18:19
User entered missing code ND - Not Done.	Andryelle Toledo (b) (4) (b) (4)	18 Feb 2021 22:18:13
User opened query 'Kindly update EDC with the remaining data from this visit. Thank you.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:29:39

US3892032

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:18:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:52:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered missing code ND - Not Done.	(b) (4) Andryelle Toledo (b) (4) (b) (4)	18 Feb 2021 22:18:13

US3892032

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:18:29

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
User entered empty.	System	18 Feb 2021 22:18:13
DataPoint set to visible.	System	15 Feb 2021 21:55:54

US3892032

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:18:29

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:52:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Kindly update EDC with the remaining data from this visit. Thank you.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:53:04
Query 'Kindly update EDC with the remaining data from this visit. Thank you.' answered with 'update' (Site from CRA).	Andryelle Toledo (b) (4) (b) (4)	18 Feb 2021 22:18:19
User entered missing code ND - Not Done.	Andryelle Toledo (b) (4) (b) (4)	18 Feb 2021 22:18:13
User opened query 'Kindly update EDC with the remaining data from this visit. Thank you.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:29:39

US3892032

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:18:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:52:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered missing code ND - Not Done.	(b) (4) Andryelle Toledo (b) (4) (b) (4)	18 Feb 2021 22:18:13

US3892032

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:18:29

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
User entered empty.	System	18 Feb 2021 22:18:13
DataPoint set to visible.	System	15 Feb 2021 21:55:54

US3892032

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
User accepted default value 'Pre-Dose (PREDOSE)'	Andryelle Toledo (b) (4) (b) (4)	18 Feb 2021 22:18:13

US3892032

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:52:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	18 Feb 2021 22:18:13

US3892032

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:52:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '15 Feb 2021'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	18 Feb 2021 22:18:13

US3892032

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:52:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '12:56'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	18 Feb 2021 22:18:13

US3892032

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
User entered '15 Feb 2021 12:56'	System	18 Feb 2021 22:18:13

US3892032

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:52:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '97.2' F	(b) (4) Andryelle Toledo (b) (4) (b) (4)	18 Feb 2021 22:18:13

US3892032

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:52:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Oral (Oral)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	18 Feb 2021 22:18:13

US3892032

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:52:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	18 Feb 2021 22:18:13
	(b) (4)	

US3892032

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:52:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '71'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	18 Feb 2021 22:18:13

US3892032

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
User entered 'bpm'	System	18 Feb 2021 22:18:13

US3892032

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:52:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '14'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	18 Feb 2021 22:18:13

US3892032

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
User entered 'breaths/min'	System	18 Feb 2021 22:18:13

US3892032

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:52:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '136'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	18 Feb 2021 22:18:13

US3892032

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
User entered 'mmHg'	System	18 Feb 2021 22:18:13

US3892032

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:52:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '86'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	18 Feb 2021 22:18:13

US3892032

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
User entered 'mmHg'	System	18 Feb 2021 22:18:13

US3892032

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:18:29

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:52:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Kindly update EDC with the remaining data from this visit. Thank you.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:53:04
Query 'Kindly update EDC with the remaining data from this visit. Thank you.' answered with 'update' (Site from CRA).	Andryelle Toledo (b) (4) (b) (4)	18 Feb 2021 22:18:19
User entered missing code ND - Not Done.	Andryelle Toledo (b) (4) (b) (4)	18 Feb 2021 22:18:13
User opened query 'Kindly update EDC with the remaining data from this visit. Thank you.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:29:39

US3892032

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:18:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:52:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered missing code ND - Not Done.	(b) (4) Andryelle Toledo (b) (4) (b) (4)	18 Feb 2021 22:18:13

US3892032

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:18:29

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
User entered empty.	System	18 Feb 2021 22:18:13
DataPoint set to visible.	System	15 Feb 2021 21:55:54

US3892032

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
User accepted default value 'Post-Dose (POSTDOSE)'	Andryelle Toledo (b) (4) (b) (4)	18 Feb 2021 22:18:13

US3892032

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:52:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	18 Feb 2021 22:18:13

US3892032

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:52:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '15 Feb 2021'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	18 Feb 2021 22:18:13

US3892032

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:52:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '13:33'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	18 Feb 2021 22:18:13

US3892032

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
User entered '15 Feb 2021 13:33'	System	18 Feb 2021 22:18:13

US3892032

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:52:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '97.8' F	(b) (4) Andryelle Toledo (b) (4) (b) (4)	18 Feb 2021 22:18:13

US3892032

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:52:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Oral (Oral)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	18 Feb 2021 22:18:13

US3892032

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:52:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	18 Feb 2021 22:18:13
	(b) (4)	

US3892032

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:52:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '73'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	18 Feb 2021 22:18:13

US3892032

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
User entered 'bpm'	System	18 Feb 2021 22:18:13

US3892032

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:52:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '14'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	18 Feb 2021 22:18:13

US3892032

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
User entered 'breaths/min'	System	18 Feb 2021 22:18:13

US3892032

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:52:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '156'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	18 Feb 2021 22:18:13

US3892032

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
User entered 'mmHg'	System	18 Feb 2021 22:18:13

US3892032

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:52:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '96'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	18 Feb 2021 22:18:13

US3892032

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
User entered 'mmHg'	System	18 Feb 2021 22:18:13

US3892032

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

Form: Physical Examination

Generated On: 10 Jun 2021 10:18:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:48:04
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	18 Feb 2021 22:18:28

US3892032

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

Form: Physical Examination

Generated On: 10 Jun 2021 10:18:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:48:04
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '15 Feb 2021'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	18 Feb 2021 22:18:28

US3892032

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

Form: Exposure

Generated On: 10 Jun 2021 10:18:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:48:22
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	18 Feb 2021 22:19:20

US3892032

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

Form: Exposure

Generated On: 10 Jun 2021 10:18:29

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:48:22
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	18 Feb 2021 22:19:20
	(b) (4)	

US3892032

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

Form: Exposure

Generated On: 10 Jun 2021 10:18:29

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 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:48:22
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	(b) (4) Andryelle Toledo (b) (4) (b) (4)	18 Feb 2021 22:19:20

US3892032

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

Form: Exposure

Generated On: 10 Jun 2021 10:18:29

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
User entered 'mRNA-1273'	System	18 Feb 2021 22:19:20
DataPoint set to visible.	System	15 Feb 2021 21:55:54

US3892032

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

Form: Exposure

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:48:22
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '15 Feb 2021'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	18 Feb 2021 22:19:20

US3892032

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

Form: Exposure

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:48:22
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '13:01'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	18 Feb 2021 22:19:20

US3892032

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

Form: Exposure

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
User entered '15 Feb 2021 13:01'	System	18 Feb 2021 22:19:20

US3892032

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

Form: Exposure

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:48:22
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Left Arm (LEFT ARM)'	Andryelle Toledo (b) (4)	18 Feb 2021 22:19:20

US3892032

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

Form: Exposure

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:48:22
User entered 'ONCE'	System	18 Feb 2021 22:19:20

US3892032

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

Form: Exposure

Generated On: 10 Jun 2021 10:18:29

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
User entered 'INTRAMUSCULAR'	System	18 Feb 2021 22:19:20

US3892032

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:49:23
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Feb 2021 21:57:26

US3892032

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:49:23
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 21:57:26

US3892032

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:49:23
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '11:39'	(b) (4), (b) (6)	15 Feb 2021 21:57:26

US3892032

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
User entered '15 Feb 2021 11:39'	System	15 Feb 2021 21:57:26

US3892032

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:18:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:49:32
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Feb 2021 21:57:42

US3892032

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:18:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:49:32
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 21:57:42

US3892032

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:18:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:49:32
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '11:49'	(b) (4), (b) (6)	15 Feb 2021 21:57:42

US3892032

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
User entered '15 Feb 2021 11:49'	System	15 Feb 2021 21:57:42

US3892032

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

Form: Continuing

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:47:39
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Feb 2021 21:57:50

US3892032

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

Form: Continuing

Generated On: 10 Jun 2021 10:18:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:51
User entered 'I'	System	15 Feb 2021 21:57:50

US3892032

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:16:29
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:13:10
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	12 Mar 2021 17:55:27

US3892032

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:16:29
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:13:10
User entered '22 Feb 2021'	Andryelle Toledo (b) (4)	12 Mar 2021 17:55:27

US3892032

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:16:29
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:13:10
User entered 'Contact Made (CONTACT MADE)'	Andryelle Toledo (b) (4) (b) (4)	12 Mar 2021 17:55:27

US3892032

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:16:29
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:13:10
User entered empty.	Andryelle Toledo (b) (4)	12 Mar 2021 17:55:27

US3892032

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:16:29
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:13:19
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	12 Mar 2021 17:55:32

US3892032

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:16:29
User entered 'I'	System	12 Mar 2021 17:55:32

US3892032

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:29

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:16:29
User entered '1'	System	12 Mar 2021 17:55:32
DataPoint set to visible.	System	12 Mar 2021 17:55:32

US3892032

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:14:18
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	12 Mar 2021 17:56:54

US3892032

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:14:18
User entered '12 Mar 2021'	Andryelle Toledo (b) (4) (b) (4)	12 Mar 2021 17:56:54

US3892032

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

[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 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:14:18
User entered 'Clinic (Clinic)'	Andryelle Toledo (b) (4) (b) (4)	12 Mar 2021 17:56:54

US3892032

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User entered 'OLD29'	System	12 Mar 2021 17:56:54

US3892032

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:21:02
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	12 Mar 2021 17:57:56

US3892032

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:21:02
User entered '12 Mar 2021'	Andryelle Toledo (b) (4) (b) (4)	12 Mar 2021 17:57:56

US3892032

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:21:02
User entered '09:30'	Andryelle Toledo (b) (4) (b) (4)	12 Mar 2021 17:57:56

US3892032

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User entered '12 Mar 2021 09:30'	System	12 Mar 2021 17:57:56

US3892032

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:21:02
User entered '99.0' F	Andryelle Toledo (b) (4) (b) (4)	12 Mar 2021 17:57:56

US3892032

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:21:02
User entered 'Oral (Oral)'	Andryelle Toledo (b) (4) (b) (4)	12 Mar 2021 17:57:56

US3892032

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:21:02
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	12 Mar 2021 17:57:56

US3892032

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:21:02
User entered '93'	Andryelle Toledo (b) (4) (b) (4)	12 Mar 2021 17:57:56

US3892032

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User entered 'bpm'	System	12 Mar 2021 17:57:56

US3892032

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:21:02
User entered '14'	Andryelle Toledo (b) (4) (b) (4)	12 Mar 2021 17:57:56

US3892032

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User entered 'breaths/min'	System	12 Mar 2021 17:57:56

US3892032

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:21:02
User entered '139'	Andryelle Toledo (b) (4) (b) (4)	12 Mar 2021 17:57:56

US3892032

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User entered 'mmHg'	System	12 Mar 2021 17:57:56

US3892032

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:21:02
User closed query 'Per CDM: Per CCG V5.0 page 76, Diastolic Blood Pressure ≥ 91 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 07:04:32
Query 'Per CDM: Per CCG V5.0 page 76, Diastolic Blood Pressure ≥ 91 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' answered with 'Per PA:NCS' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	26 Mar 2021 16:29:45
User opened query 'Per CDM: Per CCG V5.0 page 76, Diastolic Blood Pressure ≥ 91 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 07:20:34
User entered '92'	Andryelle Toledo (b) (4) (b) (4)	12 Mar 2021 17:57:56

US3892032

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User entered 'mmHg'	System	12 Mar 2021 17:57:56

US3892032

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50

US3892032

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50

US3892032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:18:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:21:26
User entered missing code ND - Not Done.	Andryelle Toledo (b) (4) (b) (4)	22 Mar 2021 17:10:47

US3892032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:18:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:21:26
User entered missing code ND - Not Done.	Andryelle Toledo (b) (4) (b) (4)	22 Mar 2021 17:10:47

US3892032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:18:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:21:26
User entered missing code ND - Not Done.	Andryelle Toledo (b) (4) (b) (4)	22 Mar 2021 17:10:47

US3892032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:18:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:21:26
User entered missing code ND - Not Done.	Andryelle Toledo (b) (4) (b) (4)	22 Mar 2021 17:10:47

US3892032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User accepted default value 'Pre-Dose (PREDOSE)'	Andryelle Toledo (b) (4) (b) (4)	22 Mar 2021 17:10:47

US3892032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:21:26
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	22 Mar 2021 17:10:47

US3892032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:21:26
User entered '12 Mar 2021'	Andryelle Toledo (b) (4) (b) (4)	22 Mar 2021 17:10:47

US3892032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:21:26
User entered '09:30'	Andryelle Toledo (b) (4) (b) (4)	22 Mar 2021 17:10:47

US3892032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User entered '12 Mar 2021 09:30'	System	22 Mar 2021 17:10:47

US3892032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:21:26
User entered '99.0' F	Andryelle Toledo (b) (4) (b) (4)	22 Mar 2021 17:10:47

US3892032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:21:26
User entered 'Oral (Oral)'	Andryelle Toledo (b) (4) (b) (4)	22 Mar 2021 17:10:47

US3892032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:21:26
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	22 Mar 2021 17:10:47

US3892032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:21:26
User entered '93'	Andryelle Toledo (b) (4) (b) (4)	22 Mar 2021 17:10:47

US3892032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User entered 'bpm'	System	22 Mar 2021 17:10:47

US3892032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:21:26
User entered '14'	Andryelle Toledo (b) (4) (b) (4)	22 Mar 2021 17:10:47

US3892032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User entered 'breaths/min'	System	22 Mar 2021 17:10:47

US3892032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:21:26
User entered '139'	Andryelle Toledo (b) (4) (b) (4)	22 Mar 2021 17:10:47

US3892032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User entered 'mmHg'	System	22 Mar 2021 17:10:47

US3892032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:21:26
User entered '92'	Andryelle Toledo (b) (4) (b) (4)	22 Mar 2021 17:10:47

US3892032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:18:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User entered 'mmHg'	System	22 Mar 2021 17:10:47

US3892032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:18:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:21:26
User entered missing code ND - Not Done.	Andryelle Toledo (b) (4) (b) (4)	22 Mar 2021 17:10:47

US3892032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:18:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:21:26
User entered missing code ND - Not Done.	Andryelle Toledo (b) (4) (b) (4)	22 Mar 2021 17:10:47

US3892032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User accepted default value 'Post-Dose (POSTDOSE)'	Andryelle Toledo (b) (4) (b) (4)	22 Mar 2021 17:10:47

US3892032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:21:26
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	22 Mar 2021 17:10:47

US3892032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:21:26
User entered '12 Mar 2021'	Andryelle Toledo (b) (4) (b) (4)	22 Mar 2021 17:10:47

US3892032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:21:26
User entered '10:37'	Andryelle Toledo (b) (4) (b) (4)	22 Mar 2021 17:10:47

US3892032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User entered '12 Mar 2021 10:37'	System	22 Mar 2021 17:10:47

US3892032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:21:26
User entered '98.1' F	Andryelle Toledo (b) (4) (b) (4)	22 Mar 2021 17:10:47

US3892032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:21:26
User entered 'Oral (Oral)'	Andryelle Toledo (b) (4) (b) (4)	22 Mar 2021 17:10:47

US3892032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:21:26
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	22 Mar 2021 17:10:47

US3892032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:21:26
User entered '81'	Andryelle Toledo (b) (4) (b) (4)	22 Mar 2021 17:10:47

US3892032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User entered 'bpm'	System	22 Mar 2021 17:10:47

US3892032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:21:26
User entered '14'	Andryelle Toledo (b) (4) (b) (4)	22 Mar 2021 17:10:47

US3892032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User entered 'breaths/min'	System	22 Mar 2021 17:10:47

US3892032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:21:26
User entered '131'	Andryelle Toledo (b) (4) (b) (4)	22 Mar 2021 17:10:47

US3892032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User entered 'mmHg'	System	22 Mar 2021 17:10:47

US3892032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:21:26
User entered '88'	Andryelle Toledo (b) (4) (b) (4)	22 Mar 2021 17:10:47

US3892032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:18:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User entered 'mmHg'	System	22 Mar 2021 17:10:47

US3892032

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:18:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:14:30
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	12 Mar 2021 17:58:14

US3892032

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:18:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:14:30
User entered '12 Mar 2021'	Andryelle Toledo (b) (4) (b) (4)	12 Mar 2021 17:58:14

US3892032

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:18:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:22:32
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	22 Mar 2021 17:12:04

US3892032

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:18:29

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:22:32
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	22 Mar 2021 17:12:04

US3892032

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:18:29

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 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:22:32
User entered empty.	Andryelle Toledo (b) (4)	22 Mar 2021 17:12:04

US3892032

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:18:29

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User entered 'MRNA-1273 OR PLACEBO'	System	22 Mar 2021 17:12:04

US3892032

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:18:29

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:22:32
User entered '12 Mar 2021'	Andryelle Toledo (b) (4) (b) (4)	22 Mar 2021 17:12:04

US3892032

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:22:32
User entered '10:05'	Andryelle Toledo (b) (4) (b) (4)	22 Mar 2021 17:12:04

US3892032

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User entered '12 Mar 2021 10:05'	System	22 Mar 2021 17:12:04

US3892032

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:22:32
User entered 'Left Arm (LEFT ARM)'	Andryelle Toledo (b) (4) (b) (4)	22 Mar 2021 17:12:04

US3892032

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:22:32
User entered 'ONCE'	System	22 Mar 2021 17:12:04

US3892032

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:18:29

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User entered 'INTRAMUSCULAR'	System	22 Mar 2021 17:12:04

US3892032

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:16:47
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	12 Mar 2021 17:58:25

US3892032

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:16:47
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	12 Mar 2021 17:58:25

US3892032

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:16:47
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	12 Mar 2021 17:58:25

US3892032

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User entered empty.	System	12 Mar 2021 17:58:25

US3892032

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:23:17
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	22 Mar 2021 17:12:22

US3892032

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:44:50
User entered 'I'	System	22 Mar 2021 17:12:22

US3892032

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:06
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:23:47
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	22 Mar 2021 17:12:35

US3892032

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:06
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:23:47
User entered '19 Mar 2021'	Andryelle Toledo (b) (4)	22 Mar 2021 17:12:35

US3892032

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:06
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:23:47
User entered 'Contact Made (CONTACT MADE)'	Andryelle Toledo (b) (4) (b) (4)	22 Mar 2021 17:12:35

US3892032

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:18:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:06
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:23:47
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	22 Mar 2021 17:12:35

US3892032

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:06
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:23:52
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	22 Mar 2021 17:12:43

US3892032

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:18:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:06
User entered 'I'	System	22 Mar 2021 17:12:43

US3892032

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:52:33
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	06 Apr 2021 17:21:30

US3892032

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:52:33
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered '06 Apr 2021'	Andryelle Toledo (b) (4)	06 Apr 2021 17:21:30

US3892032

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:52:33
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered 'Clinic (Clinic)'	Andryelle Toledo (b) (4)	06 Apr 2021 17:21:30

US3892032

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:18:29

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	06 Apr 2021 17:21:30

US3892032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:53:08
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	06 Apr 2021 17:21:58

US3892032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:53:08
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered '06 Apr 2021'	Andryelle Toledo (b) (4)	06 Apr 2021 17:21:58

US3892032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:53:08
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered '10:21'	Andryelle Toledo (b) (4)	06 Apr 2021 17:21:58

US3892032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
User entered '06 Apr 2021 10:21'	System	06 Apr 2021 17:21:58

US3892032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:53:08
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered '98.2' F	Andryelle Toledo (b) (4)	06 Apr 2021 17:21:58

US3892032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:53:08
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered 'Oral (Oral)'	Andryelle Toledo (b) (4)	06 Apr 2021 17:21:58

US3892032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:53:08
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered empty.	Andryelle Toledo (b) (4)	06 Apr 2021 17:21:58

US3892032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:53:08
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered '90'	Andryelle Toledo (b) (4)	06 Apr 2021 17:21:58

US3892032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	06 Apr 2021 17:21:58

US3892032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:53:08
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered '14'	Andryelle Toledo (b) (4)	06 Apr 2021 17:21:58

US3892032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	06 Apr 2021 17:21:58

US3892032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:53:08
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered '127'	Andryelle Toledo (b) (4)	06 Apr 2021 17:21:58

US3892032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Apr 2021 17:21:58

US3892032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:53:08
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered '81'	Andryelle Toledo (b) (4)	06 Apr 2021 17:21:58

US3892032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:18:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Apr 2021 17:21:58

US3892032

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:18:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:37
User closed query 'Kindly confirm this was completed. This is unclear per source. Thank you.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 20:58:34
Query 'Kindly confirm this was completed. This is unclear per source. Thank you.' answered with 'Update.' (Site from CRA).	Andryelle Toledo (b) (4) (b) (4)	12 Apr 2021 20:36:03
User opened query 'Kindly confirm this was completed. This is unclear per source. Thank you.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 17:53:48
User signature succeeded.	Michael Adams (b) (4) (b) (4)	12 Apr 2021 16:25:47
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	06 Apr 2021 17:22:06

US3892032

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:18:29

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:37
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered '06 Apr 2021'	Andryelle Toledo (b) (4)	06 Apr 2021 17:22:06

US3892032

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:52:44
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	06 Apr 2021 17:22:18

US3892032

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:52:44
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered '06 Apr 2021'	Andryelle Toledo (b) (4)	06 Apr 2021 17:22:18

US3892032

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:52:44
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered '10:30'	Andryelle Toledo (b) (4)	06 Apr 2021 17:22:18

US3892032

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:18:29

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

Audit	User	Time (GMT)
User entered '06 Apr 2021 10:30'	System	06 Apr 2021 17:22:18

US3892032

Folder: Unscheduled 06 Oct 2020

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 10:18:29

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:04:38
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:42:37
User closed query 'Per GCL Reconciliation: Nasopharyngeal Swab: Re-query: Response noted. As you are aware there is no place to document Unscheduled Swab collection data. GCL has a Swab sample dated 06-Oct-2020. Kindly consider initiating Covid -19 Assessment eCRF for the corresponding date(06Oct2020) and updating Swab data in the COVID Diagnostic form. Thank you.	(b) (4), (b) (6)	26 Feb 2021 07:45:24
' (Site from DM).		
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
	(b) (4)	
Query 'Per GCL Reconciliation: Nasopharyngeal Swab: Re-query: Response noted. As you are aware there is no place to document Unscheduled Swab collection data. GCL has a Swab sample dated 06-Oct-2020. Kindly consider initiating Covid -19 Assessment eCRF for the corresponding date(06Oct2020) and updating Swab data in the COVID Diagnostic form. Thank you.	Andryelle Toledo (b) (4)	11 Feb 2021 20:50:50
	(b) (4)	
' answered with 'It is already reported on 01 Oct. 2020 - Covid 19 assessment. This is not a late Nasal swab to Visit D1-Illness. The swab was collected under UNS. Thank you' (Site from DM).		
User opened query 'Per GCL Reconciliation: Nasopharyngeal Swab: Re-query: Response noted. As you are aware there is no place to document Unscheduled Swab collection data. GCL has a Swab sample dated 06-Oct-2020. Kindly consider initiating Covid -19 Assessment eCRF for the corresponding date(06Oct2020) and updating Swab data in the COVID Diagnostic form. Thank you.	(b) (4), (b) (6)	09 Feb 2021 12:29:23
' (Site from DM).		

US3892032

Folder: Unscheduled 06 Oct 2020

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 10:18:29

[Visit Date](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 06-OCT-2020 is reported under Unscheduled visit in PPD portal; however, data is missing in EDC. Kindly review if the swab sample was collected, if Yes, then please update in EDC by initiating Covid -19 Assessment eCRF for the corresponding date (06OCT2020) and updating Swab data in the COVID Diagnostic Test form as there is no provision to record Unscheduled visit for this sample. Else clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 12:29:23
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 06-OCT-2020 is reported under Unscheduled visit in PPD portal; however, data is missing in EDC. Kindly review if the swab sample was collected, if Yes, then please update in EDC by initiating Covid -19 Assessment eCRF for the corresponding date (06OCT2020) and updating Swab data in the COVID Diagnostic Test form as there is no provision to record Unscheduled visit for this sample. Else clarify, Thank you' answered with 'We collected a Nasal PCR Swab using the lab kit Day1. I called to GSS and changed the sample under the correct visit it was UNSCHEDULED. However, RAVE did not have options to check Nasal Swab Collection. Please, advise we I need to place this information on the system.' (Site from DM).	Andryelle Toledo (b) (4)	29 Jan 2021 22:53:55
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 06-OCT-2020 is reported under Unscheduled visit in PPD portal; however, data is missing in EDC. Kindly review if the swab sample was collected, if Yes, then please update in EDC by initiating Covid -19 Assessment eCRF for the corresponding date (06OCT2020) and updating Swab data in the COVID Diagnostic Test form as there is no provision to record Unscheduled visit for this sample. Else clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 12:36:58
User entered '06 Oct 2020'	Andryelle Toledo (b) (4)	21 Oct 2020 15:00:39

US3892032

Folder: **Unscheduled 06 Oct 2020**

Form: **Unscheduled Visit Assessment**

Generated On: **10 Jun 2021 10:18:29**

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:04:38
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:42:37
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
User entered 'I'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 15:00:39

US3892032

Folder: Unscheduled 06 Oct 2020

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 10:18:29

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:04:38
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:42:37
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
User entered '0'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 15:00:39

US3892032

Folder: Unscheduled 06 Oct 2020

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 10:18:29

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:04:38
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:42:37
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
User entered '0'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 15:00:39

US3892032

Folder: Unscheduled 06 Oct 2020

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 10:18:29

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:04:38
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:42:37
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
User entered '0'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 15:00:39

US3892032

Folder: Unscheduled 06 Oct 2020

Form: Physical Examination

Generated On: 10 Jun 2021 10:18:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:04:42
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:42:47
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 15:00:50

US3892032

Folder: Unscheduled 06 Oct 2020

Form: Physical Examination

Generated On: 10 Jun 2021 10:18:29

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:04:42
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:42:47
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:11:56
User entered '06 Oct 2020'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 15:00:50

US3892032

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:18:29

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:54:30
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (DAY 8 on 08SEP2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 12:27:42
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (DAY 8 on 08SEP2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' answered with 'Update ' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 15:19:25
User closed query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of HEADACHE, JOINT ACHES and MUSCLE ACHES persist beyond Day 7 (start date: Day 8; end date: Day 12). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 06:09:18
User closed query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of FATIGUE and NAUSEA/VOMITING (start date: Day 8; end date: Day 13) and symptom of CHILLS (start date: Day 8; end date: Day 9) persist beyond Day 7. Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 06:09:16

US3892032

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:18:29

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of HEADACHE, JOINT ACHES and MUSCLE ACHES persist beyond Day 7 (start date: Day 8; end date: Day 12). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' answered with 'Subject was in Convalescent Period, started on 29 Sep. 2020 to 12 Oct. 2020. D1(Illness) performed on 01 Oct. 2020. AE = viral Syndrome.' (Site from DM).	Andryelle Toledo (b) (4)	22 Feb 2021 22:50:58
Query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of FATIGUE and NAUSEA/VOMITING (start date: Day 8; end date: Day 13) and symptom of CHILLS (start date: Day 8; end date: Day 9) persist beyond Day 7. Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'Subject was in Convalescent Period, started on 29 Sep. 2020 to 12 Oct. 2020. D1(Illness) performed on 01 Oct. 2020. AE = viral Syndrome.' (Site from DM).	Andryelle Toledo (b) (4)	22 Feb 2021 22:50:54
User opened query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of HEADACHE, JOINT ACHES and MUSCLE ACHES persist beyond Day 7 (start date: Day 8; end date: Day 12). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 02:47:17
User opened query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of FATIGUE and NAUSEA/VOMITING (start date: Day 8; end date: Day 13) and symptom of CHILLS (start date: Day 8; end date: Day 9) persist beyond Day 7. Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 02:47:04

US3892032

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:18:29

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (DAY 8 on 08SEP2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6) (b) (4)	12 Feb 2021 02:45:27
	(b) (4), (b) (6) (b) (4)	16 Sep 2020 16:11:27
User entered 'Yes (Y)' reason for change: Data Entry Error	Stefanie Vasconez (b) (4) (b) (4)	10 Sep 2020 20:14:00
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	03 Sep 2020 15:50:36

US3892032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:29

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 16:11:36
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 20:17:49
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 20:17:49
	(b) (4)	
Data point term sent to Coder	System	10 Sep 2020 20:16:55
User entered 'Worsening of seasonal Allergies'	Stefanie Vasconez (b) (4)	10 Sep 2020 20:16:21
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:11:36
User entered 'No (N)'	Stefanie Vasconez (b) (4) (b) (4)	10 Sep 2020 20:16:21

US3892032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:11:36
User entered 'No (N)'	Stefanie Vasconez (b) (4) (b) (4)	10 Sep 2020 20:16:21

US3892032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:11:36
User entered 'No (N)'	Stefanie Vasconez (b) (4) (b) (4)	10 Sep 2020 20:16:21

US3892032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:11:36
User entered '7 Sep 2020'	Stefanie Vasconez (b) (4) (b) (4)	10 Sep 2020 20:16:21

US3892032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Sep 2020 21:44:08
User closed query 'kindly update EDC, per source, this time is noted as 07:00. Thank you.' (Site from CRA).	(b) (4), (b) (6)	18 Sep 2020 21:13:48
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 12:57:42
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'Time recorded on source is 07:00. Update' (Site from System).	Andryelle Toledo (b) (4)	16 Sep 2020 21:29:15
	(b) (4)	
Query 'kindly update EDC, per source, this time is noted as 07:00. Thank you.' answered with 'update' (Site from CRA).	Andryelle Toledo (b) (4)	16 Sep 2020 21:28:18
	(b) (4)	
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	16 Sep 2020 21:28:11
DataPoint Un-verified.	Andryelle Toledo (b) (4)	16 Sep 2020 21:28:11
	(b) (4)	
User entered '07:00' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	16 Sep 2020 21:28:11
	(b) (4)	
User opened query 'kindly update EDC, per source, this time is noted as 07:00. Thank you.' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 16:12:23
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:11:58
DataPoint Un-verified.	(b) (4), (b) (6)	16 Sep 2020 16:11:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:11:36
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	10 Sep 2020 20:17:44
User entered empty; reason for change Data Entry Error	Stefanie Vasconez (b) (4)	10 Sep 2020 20:17:44
	(b) (4)	
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	10 Sep 2020 20:16:21
User entered '07:00'	Stefanie Vasconez (b) (4)	10 Sep 2020 20:16:21
	(b) (4)	

PRODUCTION RELEASE (v12.003
EAB) (1725)

3241 of 4365

US3892032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '7 Sep 2020 07:00'	System	16 Sep 2020 21:28:11
User entered empty.	System	10 Sep 2020 20:17:44
User entered '7 Sep 2020 07:00'	System	10 Sep 2020 20:16:21

US3892032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:11:36
User entered 'No (N)'	Stefanie Vasconez (b) (4) (b) (4)	10 Sep 2020 20:16:21

US3892032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:29

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:11:36
User entered '8 Sep 2020'	Stefanie Vasconez (b) (4) (b) (4)	10 Sep 2020 20:16:21

US3892032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:29

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:44:08
User closed query 'Per source the time point noted for end time per source is documented as 18:00. Kindly update EDC. Thank you.' (Site from CRA).	(b) (4), (b) (6)	18 Sep 2020 21:13:51
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 12:58:12
Query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' answered with 'update' (Site from System).	Andryelle Toledo (b) (4) (b) (4)	16 Sep 2020 21:29:38
Query 'Per source the time point noted for end time per source is documented as 18:00. Kindly update EDC. Thank you.' answered with 'update' (Site from CRA).	Andryelle Toledo (b) (4) (b) (4)	16 Sep 2020 21:29:22
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	16 Sep 2020 21:28:53
DataPoint Un-verified.	Andryelle Toledo (b) (4) (b) (4)	16 Sep 2020 21:28:53
User entered '18:00' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	16 Sep 2020 21:28:53
User opened query 'Per source the time point noted for end time per source is documented as 18:00. Kindly update EDC. Thank you.' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 16:13:37
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:11:36
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	10 Sep 2020 20:17:44
User entered empty; reason for change Data Entry Error	Stefanie Vasconez (b) (4) (b) (4)	10 Sep 2020 20:17:44
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	10 Sep 2020 20:16:21
User entered '18:00'	Stefanie Vasconez (b) (4) (b) (4)	10 Sep 2020 20:16:21

US3892032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '8 Sep 2020 18:00'	System	16 Sep 2020 21:28:53
User entered empty.	System	10 Sep 2020 20:17:44
User entered '8 Sep 2020 18:00'	System	10 Sep 2020 20:16:21

US3892032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:29

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:11:36
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Stefanie Vasconez (b) (4) (b) (4)	10 Sep 2020 20:16:21

US3892032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:11:36
User entered 'No (N)'	Stefanie Vasconez (b) (4) (b) (4)	10 Sep 2020 20:16:21

US3892032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 16:11:36
User entered '0'	Stefanie Vasconez (b) (4)	10 Sep 2020 20:16:21
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:11:36
User entered '0'	Stefanie Vasconez (b) (4) (b) (4)	10 Sep 2020 20:16:21

US3892032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:11:36
User entered '0'	Stefanie Vasconez (b) (4) (b) (4)	10 Sep 2020 20:16:21

US3892032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:11:36
User entered empty.	Stefanie Vasconez (b) (4) (b) (4)	10 Sep 2020 20:16:21

US3892032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:29

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:11:36
User entered empty.	Stefanie Vasconez (b) (4) (b) (4)	10 Sep 2020 20:16:21

US3892032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:11:36
User entered empty.	Stefanie Vasconez (b) (4) (b) (4)	10 Sep 2020 20:16:21

US3892032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:11:36
User entered empty.	Stefanie Vasconez (b) (4) (b) (4)	10 Sep 2020 20:16:21

US3892032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 16:11:36
User entered '0'	Stefanie Vasconez (b) (4)	10 Sep 2020 20:16:21
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:11:36
User entered '0'	Stefanie Vasconez (b) (4) (b) (4)	10 Sep 2020 20:16:21

US3892032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:11:36
User entered '0'	Stefanie Vasconez (b) (4) (b) (4)	10 Sep 2020 20:16:21

US3892032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 16:11:36
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 20:18:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Sep 2020 20:18:10
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Stefanie Vasconez (b) (4)	10 Sep 2020 20:18:10
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	10 Sep 2020 20:16:21
	Stefanie Vasconez (b) (4)	10 Sep 2020 20:16:21
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 16:11:36
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 20:18:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Sep 2020 20:18:10
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Stefanie Vasconez (b) (4)	10 Sep 2020 20:18:10
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	10 Sep 2020 20:16:21
	Stefanie Vasconez (b) (4)	10 Sep 2020 20:16:21
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:29

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 16:11:36
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 20:18:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Sep 2020 20:18:10
User entered 'None (NONE)' reason for change: Data Entry Error	Stefanie Vasconez (b) (4)	10 Sep 2020 20:18:10
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 20:16:21
User entered empty.	Stefanie Vasconez (b) (4)	10 Sep 2020 20:16:21
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:29

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:11:36
User entered 'I'	Stefanie Vasconez (b) (4) (b) (4)	10 Sep 2020 20:16:21

US3892032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:11:36
User entered '0'	Stefanie Vasconez (b) (4) (b) (4)	10 Sep 2020 20:16:21

US3892032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:11:36
User entered '0'	Stefanie Vasconez (b) (4) (b) (4)	10 Sep 2020 20:16:21

US3892032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:29

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 16:11:36
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 20:17:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Sep 2020 20:17:44
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Stefanie Vasconez (b) (4)	10 Sep 2020 20:17:44
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 20:16:21
User entered empty.	Stefanie Vasconez (b) (4)	10 Sep 2020 20:16:21
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:11:36
User entered empty.	Stefanie Vasconez (b) (4) (b) (4)	10 Sep 2020 20:16:21

US3892032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:29

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:11:36
User entered empty.	Stefanie Vasconez (b) (4) (b) (4)	10 Sep 2020 20:16:21

US3892032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:29

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Sep 2020 20:16:21

US3892032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:18:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Sep 2020 20:16:21

US3892032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:29

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:51:14
User coded data point as SOC: Eye disorders, HLGT: Ocular infections, irritations and inflammations, HLT: Conjunctival infections, irritations and inflammations, PT: Conjunctivitis allergic, LLT: Allergic conjunctivitis - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 14:08:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 14:08:38
Data point term sent to Coder	System	21 Oct 2020 14:07:22
User entered 'Allergic Conjunctivitis'	Andryelle Toledo (b) (4)	21 Oct 2020 14:06:53
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:06:53

US3892032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:06:53

US3892032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:06:53

US3892032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered '27 Sep 2020'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:06:53

US3892032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:29

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:06:53

US3892032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 14:06:53

US3892032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:06:53

US3892032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered '28 Sep 2020'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:06:53

US3892032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:29

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:06:53

US3892032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 14:06:53

US3892032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:29

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered 'Grade 1/Mild (Grade 1/Mild)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:06:53

US3892032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:06:53

US3892032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:06:53

US3892032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:06:53

US3892032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:06:53

US3892032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:06:53

US3892032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:29

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:06:53

US3892032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:06:53

US3892032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:06:53

US3892032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:06:53

US3892032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered '0'	Andryelle Toledo (b) (4)	21 Oct 2020 14:06:53
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:06:53

US3892032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered 'Not Related (NOT RELATED)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:06:53

US3892032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered 'Not Related (NOT RELATED)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:06:53

US3892032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered 'None (NONE)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:06:53

US3892032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:29

None

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered 'I'	Andryelle Toledo (b) (4)	21 Oct 2020 14:06:53
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:06:53

US3892032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:06:53

US3892032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:29

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:06:53

US3892032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:06:53

US3892032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:29

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:06:53

US3892032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:29

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Oct 2020 14:06:53

US3892032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:18:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Oct 2020 14:06:53

US3892032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:18:29

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 18:40:21
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.	Coder Import (b) (4)	21 Dec 2020 22:39:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Dec 2020 22:39:59
Data point term sent to Coder	System	21 Dec 2020 22:38:43
DataPoint Un-verified.	Leslie Iverson (b) (4)	21 Dec 2020 22:38:17
	(b) (4)	
Coding entries removed.	Leslie Iverson (b) (4)	21 Dec 2020 22:38:17
	(b) (4)	
User entered 'Viral Syndrome' reason for change: Data Entry Error	Leslie Iverson (b) (4)	21 Dec 2020 22:38:17
	(b) (4)	
User closed query 'Per MM: Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 06:34:29
Query 'Per MM: Please confirm if this subject was assessed for potential COVID-19 infection.' answered with 'yes' (Site from DM).	Andryelle Toledo (b) (4)	02 Dec 2020 02:14:49
	(b) (4)	
User opened query 'Per MM: Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 18:31:35
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:31:35
User closed query 'Per CDM: Please kindly review and confirm the AE event term name, as, for the same event with same start dates, in the corresponding Con Med indication, it is mentioned as "ACUTE RESPIRATORY INFECTION" in ConMed eCRF page, and in AE eCRF as "UPPER RESPIRATORY TRACT INFECTION", if there are two different events, kindly consider adding another AE log line with different start date. Please review and reconcile accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 12:18:04

US3892032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:18:29

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory tract infection - version MedDRA\23.0.	Coder Import (b) (4)	19 Nov 2020 22:58:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Nov 2020 22:58:54
Data point term sent to Coder	System	19 Nov 2020 22:58:06
Query 'Per CDM: Please kindly review and confirm the AE event term name, as, for the same event with same start dates, in the corresponding Con Med indication, it is mentioned as "ACUTE RESPIRATORY INFECTION" in ConMed eCRF page, and in AE eCRF as "UPPER RESPIRATORY TRACT INFECTION", if there are two different events, kindly consider adding another AE log line with different start date. Please review and reconcile accordingly. Thank you.' answered with 'update' (Site from DM).	Andryelle Toledo (b) (4)	19 Nov 2020 22:58:03
DataPoint Un-verified.	Andryelle Toledo (b) (4)	19 Nov 2020 22:57:51
Coding entries removed.	Andryelle Toledo (b) (4)	19 Nov 2020 22:57:51
User entered 'UPPER RESPIRATORY TRACT INFECTION' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	19 Nov 2020 22:57:51
User opened query 'Per CDM: Please kindly review and confirm the AE event term name, as, for the same event with same start dates, in the corresponding Con Med indication, it is mentioned as "ACUTE RESPIRATORY INFECTION" in ConMed eCRF page, and in AE eCRF as "UPPER RESPIRATORY TRACT INFECTION", if there are two different events, kindly consider adding another AE log line with different start date. Please review and reconcile accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 06:22:43
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:51:14

US3892032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:18:29

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 14:09:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 14:09:43
Data point term sent to Coder	System	21 Oct 2020 14:08:24
User entered 'Upper respiratory infection'	Andryelle Toledo (b) (4)	21 Oct 2020 14:07:59

US3892032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:18:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:07:59

US3892032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:18:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:07:59

US3892032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:18:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:07:59

US3892032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered '29 Sep 2020'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:07:59

US3892032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:18:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 11:51:17
	(b) (4), (b) (6)	28 Oct 2020 18:51:14
Query 'Data is required. Please provide.' answered with 'Time is UNK' (Site from System).	Andryelle Toledo (b) (4)	21 Oct 2020 14:08:09
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	
User entered empty.	System	21 Oct 2020 14:07:59
	Andryelle Toledo (b) (4)	21 Oct 2020 14:07:59
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:18:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 14:07:59

US3892032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered 'No (N)' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	27 Oct 2020 21:04:47
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:07:59

US3892032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:18:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered '12 Oct 2020' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	27 Oct 2020 21:04:47
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	21 Oct 2020 14:07:59
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:18:29

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	30 Oct 2020 11:51:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:51:14
Query 'Data is required. Please provide.' answered with 'Time is UNK' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 21:04:55
User opened query 'Data is required. Please provide.' (Site from System).	Andryelle Toledo (b) (4)	27 Oct 2020 21:04:47
User entered empty.	System	21 Oct 2020 14:07:59

US3892032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:18:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 14:07:59

US3892032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:18:29

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:07:59

US3892032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:18:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:07:59

US3892032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:18:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:07:59

US3892032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:18:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:07:59

US3892032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:18:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:07:59

US3892032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:18:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:07:59

US3892032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:18:29

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:07:59

US3892032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:18:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:07:59

US3892032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:18:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:07:59

US3892032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:18:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:07:59

US3892032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:18:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:07:59

US3892032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:18:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:07:59

US3892032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:18:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered 'Not Related (NOT RELATED)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:07:59

US3892032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:18:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered 'Not Related (NOT RELATED)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:07:59

US3892032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:18:29

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 20:31:21
User closed query 'Per CDM: Action taken with investigational product is 'None', however, per CCGs Version 2.0 page 35, 'Not Applicable' should be selected if the Adverse Event started after last dose of investigational product. Please clarify and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 16:04:41
Query 'Per CDM: Action taken with investigational product is 'None', however, per CCGs Version 2.0 page 35, 'Not Applicable' should be selected if the Adverse Event started after last dose of investigational product. Please clarify and update as appropriate. Thank you.' answered with 'Updated to N/A' (Site from DM).	Leslie Iverson (b) (4)	11 Nov 2020 21:22:26
	(b) (4)	
DataPoint Un-verified.	Leslie Iverson (b) (4)	11 Nov 2020 21:22:05
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Leslie Iverson (b) (4)	11 Nov 2020 21:22:05
	(b) (4)	
User opened query 'Per CDM: Action taken with investigational product is 'None', however, per CCGs Version 2.0 page 35, 'Not Applicable' should be selected if the Adverse Event started after last dose of investigational product. Please clarify and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 11:20:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered 'None (NONE)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:07:59
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:18:29

None

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:07:59

US3892032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Per CDM : Please note that Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Dec 2020 08:21:49
Query 'Per CDM : Please note that Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate. Thank you.' answered with 'Update Conmed #11 and 12 si related with this AE' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	31 Dec 2020 00:53:51
User opened query 'Per CDM : Please note that Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 15:57:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered 'I'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:07:59

US3892032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:07:59

US3892032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:18:29

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 11:51:25
	(b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Andryelle Toledo (b) (4)	27 Oct 2020 21:04:47
Data Entry Error	(b) (4)	
Query 'Data is required. Please complete.' answered with 'AE is ongoing' (Site from System).	Andryelle Toledo (b) (4)	21 Oct 2020 14:08:21
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	21 Oct 2020 14:07:59
	Andryelle Toledo (b) (4)	21 Oct 2020 14:07:59
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:18:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:07:59

US3892032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:18:29

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:51:14
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:07:59

US3892032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:18:29

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Oct 2020 14:07:59

US3892032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:18:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Oct 2020 14:07:59

US3892032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:18:29

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 20:34:17
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory tract infection - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 23:01:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 23:01:07
Data point term sent to Coder	System	19 Nov 2020 23:00:08
User entered 'UPPER RESPIRATORY TRACT INFECTION'	Andryelle Toledo (b) (4)	19 Nov 2020 22:59:22
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:18:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 22:59:22

US3892032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:18:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 22:59:22

US3892032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:18:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 22:59:22

US3892032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered '14 Nov 2020'	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 22:59:22

US3892032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:18:29

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 22:59:22

US3892032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:18:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 22:59:22

US3892032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:26:15
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	24 Nov 2020 18:11:46
DataPoint Un-verified.	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:46
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:46
	(b) (4)	
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	24 Nov 2020 18:11:39
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:17
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 23:09:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 23:09:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	19 Nov 2020 23:09:52
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 22:59:22
User entered empty.	Andryelle Toledo (b) (4)	19 Nov 2020 22:59:22
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:18:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:26:15
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	24 Nov 2020 18:11:39
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	24 Nov 2020 18:11:39
DataPoint Un-verified.	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:39
	(b) (4)	
User entered '19 Nov 2020' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:39
	(b) (4)	
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	24 Nov 2020 18:11:05
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered empty.	Andryelle Toledo (b) (4)	19 Nov 2020 22:59:22
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:18:29

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 22:59:22

US3892032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:18:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 22:59:22

US3892032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:18:29

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:26:15
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 18:11:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Nov 2020 18:11:05
DataPoint Un-verified.	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:05
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:05
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:17
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 22:59:22
User entered empty.	Andryelle Toledo (b) (4)	19 Nov 2020 22:59:22
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:18:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:26:15
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 18:11:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Nov 2020 18:11:05
DataPoint Un-verified.	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:05
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:05
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:17
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 22:59:22
User entered empty.	Andryelle Toledo (b) (4)	19 Nov 2020 22:59:22
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:18:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered '0'	Andryelle Toledo (b) (4)	19 Nov 2020 22:59:22
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:18:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 22:59:22

US3892032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:18:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 22:59:22

US3892032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:18:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 22:59:22

US3892032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:18:29

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 22:59:22

US3892032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:18:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 22:59:22

US3892032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:18:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 22:59:22

US3892032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:18:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 22:59:22

US3892032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:18:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 22:59:22

US3892032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:18:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 22:59:22

US3892032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:18:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 20:34:17
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 23:09:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 23:09:43
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	19 Nov 2020 23:09:43
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	19 Nov 2020 22:59:22
	Andryelle Toledo (b) (4)	19 Nov 2020 22:59:22
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:18:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 20:34:17
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 23:09:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 23:09:43
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	19 Nov 2020 23:09:43
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 22:59:22
User entered empty.	Andryelle Toledo (b) (4)	19 Nov 2020 22:59:22
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:18:29

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 20:34:17
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 23:09:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 23:09:43
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	19 Nov 2020 23:09:43
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 22:59:22
User entered empty.	Andryelle Toledo (b) (4)	19 Nov 2020 22:59:22
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:18:29

None

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). Comment added 'update'.	System	25 Nov 2020 14:53:34
	Andryelle Toledo (b) (4)	24 Nov 2020 18:14:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:17
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). User entered '0'	System	19 Nov 2020 22:59:22
	Andryelle Toledo (b) (4)	19 Nov 2020 22:59:22
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 18:39:17
DataPoint Un-verified.	Leslie Iverson (b) (4)	25 Nov 2020 14:53:34
	(b) (4)	
User entered '1' reason for change: Per Query Resolution	Leslie Iverson (b) (4)	25 Nov 2020 14:53:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered '0'	Andryelle Toledo (b) (4)	19 Nov 2020 22:59:22
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 22:59:22

US3892032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:18:29

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Per CDM Re-query: Per CCG version 2.0, page 38, If AE ongoing is marked as "YES" then AE outcome must be "Not Recovered/Not Resolved" or "Recovering/Resolving" please reconcile and update Outcome as appropriate. Thank you' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 01:45:20
Query 'Per CDM Re-query: Per CCG version 2.0, page 38, If AE ongoing is marked as "YES" then AE outcome must be "Not Recovered/Not Resolved" or "Recovering/Resolving" please reconcile and update Outcome as appropriate. Thank you' answered with 'update' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6) Andryelle Toledo (b) (4)	24 Nov 2020 19:26:15 24 Nov 2020 18:12:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error DataPoint Verified.	Andryelle Toledo (b) (4) Andryelle Toledo (b) (4)	24 Nov 2020 18:11:05 24 Nov 2020 18:11:05
User closed query 'Data is required. Please complete.' (Site from System). User opened query 'Per CDM Re-query: Per CCG version 2.0, page 38, If AE ongoing is marked as "YES" then AE outcome must be "Not Recovered/Not Resolved" or "Recovering/Resolving" please reconcile and update Outcome as appropriate. Thank you' (Site from DM). Query 'Data is required. Please complete.' answered with 'ongoing' (Site from System). User opened query 'Data is required. Please complete.' (Site from System). User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6) Andryelle Toledo (b) (4) System Andryelle Toledo (b) (4)	23 Nov 2020 20:34:17 23 Nov 2020 01:16:45 23 Nov 2020 01:16:42 19 Nov 2020 23:10:01 19 Nov 2020 22:59:22 19 Nov 2020 22:59:22

US3892032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:18:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 22:59:22

US3892032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:18:29

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 22:59:22

US3892032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:18:29

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Nov 2020 18:11:05

US3892032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:18:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Nov 2020 22:59:22

US3892032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:18:29

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:28:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Esophageal reflux aggravated - version MedDRA\23.0.	Coder Import (b) (4)	17 Feb 2021 16:03:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	17 Feb 2021 16:03:00
Data point term sent to Coder	System	17 Feb 2021 16:02:29
DataPoint Un-verified.	Andryelle Toledo (b) (4)	17 Feb 2021 16:02:22
Coding entries removed.	(b) (4)	
	Andryelle Toledo (b) (4)	17 Feb 2021 16:02:22
	(b) (4)	
User entered 'Worsening of Gastroesophageal Reflux Disease' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	17 Feb 2021 16:02:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 20:34:17
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Urticaria, LLT: Rash urticaria-like - version MedDRA\23.0.	Coder Import (b) (4)	20 Nov 2020 03:33:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	20 Nov 2020 03:33:03
Data point term sent to Coder	System	19 Nov 2020 23:15:19
Coding entries removed.	Andryelle Toledo (b) (4)	19 Nov 2020 23:14:59
	(b) (4)	
User entered 'RASH ON MID BACK (URTICARIA)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	19 Nov 2020 23:14:59
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Urticaria, LLT: Urticaria - version MedDRA\23.0.	Coder Import (b) (4)	19 Nov 2020 23:01:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Nov 2020 23:01:49
Data point term sent to Coder	System	19 Nov 2020 23:01:09
User entered 'Urticaria'	Andryelle Toledo (b) (4)	19 Nov 2020 23:00:53
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:18:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 23:00:53

US3892032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:18:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 23:00:53

US3892032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:18:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 23:00:53

US3892032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:28:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Un-verified.	Andryelle Toledo (b) (4)	17 Feb 2021 16:02:22
User entered '15 Oct 2020' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	17 Feb 2021 16:02:22
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:19:46
User closed query 'Per source start date is noted as 12NOV2020, kindly confirm if this should be updated and update accordingly. Per source, time is UNK, kindly update that data point as well. Thank you.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 20:19:43
Query 'Per source start date is noted as 12NOV2020, kindly confirm if this should be updated and update accordingly. Per source, time is UNK, kindly update that data point as well. Thank you.' answered with 'update' (Site from CRA).	Andryelle Toledo (b) (4)	24 Nov 2020 20:13:27
DataPoint Un-verified.	Andryelle Toledo (b) (4)	24 Nov 2020 20:13:19
User entered '12 Nov 2020' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	24 Nov 2020 20:13:19
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:17
User opened query 'Per source start date is noted as 12NOV2020, kindly confirm if this should be updated and update accordingly. Per source, time is UNK, kindly update that data point as well. Thank you.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 20:34:00
User entered '16 Nov 2020'	Andryelle Toledo (b) (4)	19 Nov 2020 23:00:53

US3892032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:18:29

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 23:00:53

US3892032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:18:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 23:00:53

US3892032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 18:40:21
DataPoint Un-verified.		
	Leslie Iverson (b) (4)	21 Dec 2020 21:36:04
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Leslie Iverson (b) (4)	21 Dec 2020 21:36:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	19 Nov 2020 23:00:53
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:18:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:26:35
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
User closed query 'Per source end date is noted as 15NOV2020, kindly confirm if EDC needs updated and update accordingly. Thank you.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:01:10
Query 'Per source end date is noted as 15NOV2020, kindly confirm if EDC needs updated and update accordingly. Thank you.' answered with 'update' (Site from CRA).	Andryelle Toledo (b) (4) (b) (4)	03 Mar 2021 16:53:17
DataPoint Un-verified.	Andryelle Toledo (b) (4) (b) (4)	03 Mar 2021 16:53:11
Signature has been broken.	Andryelle Toledo (b) (4) (b) (4)	03 Mar 2021 16:53:11
User entered '15 Nov 2020' reason for change: New Information	Andryelle Toledo (b) (4) (b) (4)	03 Mar 2021 16:53:11
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:29:55
User opened query 'Per source end date is noted as 15NOV2020, kindly confirm if EDC needs updated and update accordingly. Thank you.' (Site from CRA).	(b) (4), (b) (6)	02 Mar 2021 21:29:44
User signature succeeded.	Michael Adams (b) (4) (b) (4)	23 Feb 2021 18:10:34
DataPoint Un-verified.	Andryelle Toledo (b) (4) (b) (4)	17 Feb 2021 16:02:22
User entered '16 Nov 2020' reason for change: New Information	Andryelle Toledo (b) (4) (b) (4)	17 Feb 2021 16:02:22
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:40:00
DataPoint Un-verified.	Leslie Iverson (b) (4) (b) (4)	21 Dec 2020 21:36:04
User entered '28 Nov 2020' reason for change: New Information	Leslie Iverson (b) (4) (b) (4)	21 Dec 2020 21:36:04
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 23:00:53

US3892032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:18:29

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 23:00:53

US3892032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:18:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 23:00:53

US3892032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:18:29

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:29:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Un-verified.	Andryelle Toledo (b) (4)	17 Feb 2021 16:02:22
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	17 Feb 2021 16:02:22
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered 'Grade 1/Mild (Grade 1/Mild)'	Andryelle Toledo (b) (4)	19 Nov 2020 23:00:53

US3892032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:18:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 23:00:53

US3892032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:18:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 23:00:53

US3892032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:18:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 23:00:53

US3892032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:18:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 23:00:53

US3892032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:18:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 23:00:53

US3892032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:18:29

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 23:00:53

US3892032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:18:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 23:00:53

US3892032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:18:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 23:00:53

US3892032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:18:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 23:00:53

US3892032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:18:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 23:00:53

US3892032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:18:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 23:00:53

US3892032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:18:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 20:34:17
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 23:01:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 23:01:08
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	19 Nov 2020 23:01:08
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 23:00:53
User entered empty.	Andryelle Toledo (b) (4)	19 Nov 2020 23:00:53
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:18:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 20:34:17
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 23:01:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 23:01:08
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	19 Nov 2020 23:01:08
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 23:00:53
User entered empty.	Andryelle Toledo (b) (4)	19 Nov 2020 23:00:53
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:18:29

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:17
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 23:01:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 23:01:08
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 23:01:08
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 23:00:53
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 23:00:53

US3892032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:18:29

None

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 23:00:53

US3892032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered 'I'	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 23:00:53

US3892032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 23:00:53

US3892032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:18:29

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 18:40:06
DataPoint Un-verified.	Leslie Iverson (b) (4)	21 Dec 2020 21:36:04
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Leslie Iverson (b) (4)	21 Dec 2020 21:36:04
New Information	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:00:03
User closed query 'Per CDM Re-query: Per CCG version 2.0, page 38, If AE ongoing is marked as "YES" then AE outcome must be "Not Recovered/Not Resolved" or "Recovering/Resolving" please reconcile and update Outcome as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 06:49:25
Query 'Per CDM Re-query: Per CCG version 2.0, page 38, If AE ongoing is marked as "YES" then AE outcome must be "Not Recovered/Not Resolved" or "Recovering/Resolving" please reconcile and update Outcome as appropriate. Thank you' answered with 'per subject rash was gone but was still on treatment' (Site from DM).	Leslie Iverson (b) (4)	25 Nov 2020 14:58:49
	(b) (4)	
DataPoint Un-verified.	Leslie Iverson (b) (4)	25 Nov 2020 14:57:36
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Leslie Iverson (b) (4)	25 Nov 2020 14:57:36
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:17
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 01:18:50
User opened query 'Per CDM Re-query: Per CCG version 2.0, page 38, If AE ongoing is marked as "YES" then AE outcome must be "Not Recovered/Not Resolved" or "Recovering/Resolving" please reconcile and update Outcome as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 01:18:48
Query 'Data is required. Please complete.' answered with 'Ongoing' (Site from System).	Andryelle Toledo (b) (4)	19 Nov 2020 23:01:16
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 23:00:53

PRODUCTION RELEASE (v12.003
EAB) (1725)

3403 of 4365

US3892032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:18:29

[Outcome](#)

Audit	User	Time (GMT)
User entered empty.	Andryelle Toledo (b) (4)	19 Nov 2020 23:00:53
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:18:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 23:00:53

US3892032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:18:29

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:04
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Un-verified.	Andryelle Toledo (b) (4)	17 Feb 2021 16:05:16
User entered 'SUBJECT REPORTED THAT ACID REFLUX STARTED AWAKENING HER AT NIGHT SOMETIME IN OCTOBER. HER HCP INCREASED THE OMEPRAZOLE DOSAGE AND SYMPTOMS RETURNED TO BASELINE.' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	17 Feb 2021 16:05:16
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:34:17
User entered empty.	Andryelle Toledo (b) (4)	19 Nov 2020 23:00:53

US3892032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:18:29

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Nov 2020 23:00:53

US3892032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:18:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Nov 2020 23:00:53

US3892032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:18:29

[AEID](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	17 Feb 2021 16:00:03
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:23

US3892032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:18:29

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Urticaria, LLT: Rash urticaria-like - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 16:04:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 16:04:02
Data point term sent to Coder	System	17 Feb 2021 16:03:35
User entered 'RASH ON MID BACK (URTICARIA)'	Andryelle Toledo (b) (4)	17 Feb 2021 16:03:14
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	17 Feb 2021 16:00:03
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:23

US3892032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:18:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	17 Feb 2021 16:03:14
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	17 Feb 2021 16:00:03
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:23

US3892032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:18:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'No (N)'	Andryelle Toledo (b) (4)	17 Feb 2021 16:03:14
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	17 Feb 2021 16:00:03
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:23

US3892032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:18:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'No (N)'	Andryelle Toledo (b) (4)	17 Feb 2021 16:03:14
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	17 Feb 2021 16:00:03
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:23

US3892032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '12 Nov 2020'	Andryelle Toledo (b) (4)	17 Feb 2021 16:03:14
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	17 Feb 2021 16:00:03
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:23

US3892032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:18:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	17 Feb 2021 16:03:14
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	17 Feb 2021 16:00:03
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:23

US3892032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:18:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 16:03:14
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	17 Feb 2021 16:00:03
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:23
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'No (N)'	Andryelle Toledo (b) (4)	17 Feb 2021 16:03:14
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	17 Feb 2021 16:00:03
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:23

US3892032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:18:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '28 Nov 2020' reason for change: Data Entry Error	(b) (4)	17 Feb 2021 16:04:49
User entered '16 Nov 2020'	Andryelle Toledo (b) (4)	17 Feb 2021 16:03:14
DataPoint activated with code reason code Data required.	(b) (4)	17 Feb 2021 16:00:03
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:23

US3892032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:18:29

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	17 Feb 2021 16:03:14
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	17 Feb 2021 16:00:03
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:23

US3892032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:18:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 16:03:14
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	17 Feb 2021 16:00:03
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:23
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:18:29

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Grade 1/Mild (Grade 1/Mild)'	Andryelle Toledo (b) (4)	17 Feb 2021 16:03:14
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	17 Feb 2021 16:00:03
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:23

US3892032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:18:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'No (N)'	Andryelle Toledo (b) (4)	17 Feb 2021 16:03:14
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	17 Feb 2021 16:00:03
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:23

US3892032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:18:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '0'	Andryelle Toledo (b) (4)	17 Feb 2021 16:03:14
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	17 Feb 2021 16:00:03
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:23

US3892032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:18:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '0'	Andryelle Toledo (b) (4)	17 Feb 2021 16:03:14
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	17 Feb 2021 16:00:03
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:23

US3892032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:18:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '0'	Andryelle Toledo (b) (4)	17 Feb 2021 16:03:14
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	17 Feb 2021 16:00:03
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:23

US3892032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:18:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	17 Feb 2021 16:03:14
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	17 Feb 2021 16:00:03
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:23

US3892032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:18:29

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	17 Feb 2021 16:03:14
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	17 Feb 2021 16:00:03
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:23

US3892032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:18:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	17 Feb 2021 16:03:14
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	17 Feb 2021 16:00:03
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:23

US3892032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:18:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	17 Feb 2021 16:03:14
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	17 Feb 2021 16:00:03
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:23

US3892032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:18:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '0'	Andryelle Toledo (b) (4)	17 Feb 2021 16:03:14
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	17 Feb 2021 16:00:03
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:23

US3892032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:18:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '0'	Andryelle Toledo (b) (4)	17 Feb 2021 16:03:14
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	17 Feb 2021 16:00:03
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:23

US3892032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:18:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '0'	Andryelle Toledo (b) (4)	17 Feb 2021 16:03:14
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	17 Feb 2021 16:00:03
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:23

US3892032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:18:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Not Related (NOT RELATED)'	Andryelle Toledo (b) (4)	17 Feb 2021 16:03:14
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	17 Feb 2021 16:00:03
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:23

US3892032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:18:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Not Related (NOT RELATED)'	Andryelle Toledo (b) (4)	17 Feb 2021 16:03:14
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	17 Feb 2021 16:00:03
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:23

US3892032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:18:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Andryelle Toledo (b) (4)	17 Feb 2021 16:03:14
	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	17 Feb 2021 16:00:03
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:23
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:18:29

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '0'	Andryelle Toledo (b) (4)	17 Feb 2021 16:03:14
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	17 Feb 2021 16:00:03
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:23

US3892032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'I'	Andryelle Toledo (b) (4)	17 Feb 2021 16:03:14
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	17 Feb 2021 16:00:03
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:23

US3892032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '0'	Andryelle Toledo (b) (4)	17 Feb 2021 16:03:14
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	17 Feb 2021 16:00:03
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:23

US3892032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:18:29

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Andryelle Toledo (b) (4)	17 Feb 2021 16:03:14
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	17 Feb 2021 16:00:03
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:23

US3892032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:18:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	(b) (4)	17 Feb 2021 16:03:14
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	17 Feb 2021 16:00:03
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:23

US3892032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:18:29

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered empty.	Andryelle Toledo (b) (4)	17 Feb 2021 16:03:14
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	17 Feb 2021 16:00:03
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:23

US3892032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:18:29

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	17 Feb 2021 16:03:14
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	17 Feb 2021 16:00:03
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:23
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:18:29

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	17 Feb 2021 16:03:14
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	17 Feb 2021 16:00:03
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:23
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:18:29

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	17 Feb 2021 16:00:03
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	24 Nov 2020 18:11:23

US3892032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:18:29

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Acute sinusitis, LLT: Acute sinusitis - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 16:05:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 16:05:00
Data point term sent to Coder	System	17 Feb 2021 16:04:36
DataPoint Un-verified.	Andryelle Toledo (b) (4)	17 Feb 2021 16:04:16
Coding entries removed.	Andryelle Toledo (b) (4)	17 Feb 2021 16:04:16
User entered 'Acute Sinusitis' reason for change:	Andryelle Toledo (b) (4)	17 Feb 2021 16:04:16
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:40:21
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Esophageal reflux aggravated - version MedDRA\\23.0.	Coder Import (b) (4)	21 Dec 2020 21:55:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Dec 2020 21:55:52
Data point term sent to Coder	System	21 Dec 2020 21:54:55
User entered 'Worsening of gastroesophageal reflux disease'	Leslie Iverson (b) (4)	21 Dec 2020 21:54:06

US3892032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:18:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:40:21
User entered 'Yes (Y)'	Leslie Iverson (b) (4) (b) (4)	21 Dec 2020 21:54:06

US3892032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:18:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:40:21
User entered 'No (N)'	Leslie Iverson (b) (4) (b) (4)	21 Dec 2020 21:54:06

US3892032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:18:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:40:21
User entered 'No (N)'	Leslie Iverson (b) (4) (b) (4)	21 Dec 2020 21:54:06

US3892032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Un-verified.	Andryelle Toledo (b) (4)	17 Feb 2021 16:04:16
User entered '11 Jan 2021' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	17 Feb 2021 16:04:16
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:40:21
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Dec 2020 21:55:16
User entered '15 Oct 2020' reason for change: Data Entry Error	Leslie Iverson (b) (4)	21 Dec 2020 21:55:16
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Dec 2020 21:54:06
User entered 'UN Oct 2020' (non-conformant).	Leslie Iverson (b) (4)	21 Dec 2020 21:54:06

US3892032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:18:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:40:21
User entered empty.	Leslie Iverson (b) (4) (b) (4)	21 Dec 2020 21:54:06

US3892032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:18:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Dec 2020 21:54:06

US3892032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:40:21
User entered 'No (N)'	Leslie Iverson (b) (4) (b) (4)	21 Dec 2020 21:54:06

US3892032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:18:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '21 Jan 2021' reason for change: Data Entry Error	(b) (4)	17 Feb 2021 16:04:26
DataPoint Un-verified.	Andryelle Toledo (b) (4)	17 Feb 2021 16:04:16
User entered '12 Jan 2021' reason for change: Data Entry Error	(b) (4)	17 Feb 2021 16:04:16
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:40:21
User entered '15 Nov 2020'	Leslie Iverson (b) (4)	21 Dec 2020 21:54:06

US3892032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:18:29

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:40:21
User entered empty.	Leslie Iverson (b) (4) (b) (4)	21 Dec 2020 21:54:06

US3892032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:18:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Dec 2020 21:54:06

US3892032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:18:29

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:40:21
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Leslie Iverson (b) (4) (b) (4)	21 Dec 2020 21:54:06

US3892032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:18:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:40:21
User entered 'No (N)'	Leslie Iverson (b) (4) (b) (4)	21 Dec 2020 21:54:06

US3892032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:18:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:40:21
User entered '0'	Leslie Iverson (b) (4) (b) (4)	21 Dec 2020 21:54:06

US3892032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:18:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:40:21
User entered '0'	Leslie Iverson (b) (4) (b) (4)	21 Dec 2020 21:54:06

US3892032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:18:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:40:21
User entered '0'	Leslie Iverson (b) (4) (b) (4)	21 Dec 2020 21:54:06

US3892032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:18:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:40:21
User entered empty.	Leslie Iverson (b) (4) (b) (4)	21 Dec 2020 21:54:06

US3892032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:18:29

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:40:21
User entered empty.	Leslie Iverson (b) (4) (b) (4)	21 Dec 2020 21:54:06

US3892032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:18:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:40:21
User entered empty.	Leslie Iverson (b) (4) (b) (4)	21 Dec 2020 21:54:06

US3892032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:18:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:40:21
User entered empty.	Leslie Iverson (b) (4) (b) (4)	21 Dec 2020 21:54:06

US3892032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:18:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:40:21
User entered '0'	Leslie Iverson (b) (4) (b) (4)	21 Dec 2020 21:54:06

US3892032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:18:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:40:21
User entered '0'	Leslie Iverson (b) (4) (b) (4)	21 Dec 2020 21:54:06

US3892032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:18:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 18:40:21
User entered '0'	Leslie Iverson (b) (4)	21 Dec 2020 21:54:06
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:18:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 18:40:21
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 21:55:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Dec 2020 21:55:16
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Leslie Iverson (b) (4)	21 Dec 2020 21:55:16
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 21:54:06
User entered empty.	Leslie Iverson (b) (4)	21 Dec 2020 21:54:06
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:18:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 18:40:21
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 21:55:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Dec 2020 21:55:16
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Leslie Iverson (b) (4)	21 Dec 2020 21:55:16
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 21:54:06
User entered empty.	Leslie Iverson (b) (4)	21 Dec 2020 21:54:06
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:18:29

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 18:40:21
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 21:55:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Dec 2020 21:55:16
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Leslie Iverson (b) (4)	21 Dec 2020 21:55:16
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 21:54:06
User entered empty.	Leslie Iverson (b) (4)	21 Dec 2020 21:54:06
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:18:29

None

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 18:40:21
User entered '0'	Leslie Iverson (b) (4)	21 Dec 2020 21:54:06
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:40:21
User closed query 'Per CDM: Requery: Response noted. However conmed #8 (Omeprazole) was taken till 12 Nov 2020 for indication 'GASTROESOPHAGEAL REFLUX DISEASE'. Kindly confirm the medical management done for the 'WORSENING OF GASTROESOPHAGEAL REFLUX DISEASE' which last till 15 Nov 2020.Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 07:23:12
Query 'Per CDM: Requery: Response noted. However conmed #8 (Omeprazole) was taken till 12 Nov 2020 for indication 'GASTROESOPHAGEAL REFLUX DISEASE'. Kindly confirm the medical management done for the 'WORSENING OF GASTROESOPHAGEAL REFLUX DISEASE' which last till 15 Nov 2020.Thank you.' answered with 'Subject reported an increase in Omeprazole dosage from 40 mg QD to 40 mg BID due to worsening GERD.' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	05 Jan 2021 02:34:04
User opened query 'Per CDM: Requery: Response noted. However conmed #8 (Omeprazole) was taken till 12 Nov 2020 for indication 'GASTROESOPHAGEAL REFLUX DISEASE'. Kindly confirm the medical management done for the 'WORSENING OF GASTROESOPHAGEAL REFLUX DISEASE' which last till 15 Nov 2020.Thank you.' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 08:33:12
User closed query 'Per CDM : Please note that Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 08:33:12

US3892032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
Query 'Per CDM : Please note that Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate. Thank you.' answered with 'The conmed related with this AE is #8 (OMEPRAZOLE)' (Site from DM).	Andryelle Toledo (b) (4)	31 Dec 2020 00:56:51
User opened query 'Per CDM : Please note that Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 15:58:10
User entered 'I'	Leslie Iverson (b) (4)	21 Dec 2020 21:54:06

US3892032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:40:21
User entered '0'	Leslie Iverson (b) (4) (b) (4)	21 Dec 2020 21:54:06

US3892032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:18:29

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:40:21
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Leslie Iverson (b) (4) (b) (4)	21 Dec 2020 21:54:06

US3892032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:18:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:40:21
User entered empty.	Leslie Iverson (b) (4) (b) (4)	21 Dec 2020 21:54:06

US3892032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:18:29

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Un-verified.	Andryelle Toledo (b) (4)	17 Feb 2021 16:04:16
User entered empty; reason for change Data Entry Error	Andryelle Toledo (b) (4)	17 Feb 2021 16:04:16
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:40:21
User entered 'Subject reported that acid reflux started awakening her at night sometime in October. Her HCP increased the omeprazole dosage and symptoms returned to baseline.'	Leslie Iverson (b) (4)	21 Dec 2020 21:54:06

US3892032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:18:29

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Dec 2020 21:54:06

US3892032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:18:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Dec 2020 21:54:06

US3892032

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:18:29

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Feb 2021 07:36:45
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Bronchitis, LLT: Acute bronchitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 16:07:02
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 16:07:02
Data point term sent to Coder	System	17 Feb 2021 16:06:40
DataPoint Un-verified.	Andryelle Toledo (b) (4)	17 Feb 2021 16:06:07
Coding entries removed.	(b) (4) Andryelle Toledo (b) (4)	17 Feb 2021 16:06:07
User entered 'ACUTE Bronchitis' reason for change:	(b) (4)	
Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	17 Feb 2021 16:06:07
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' answered with 'Yes, subject was assessed for potential Covid-19' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	16 Feb 2021 17:32:56
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 12:22:43
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:51:04
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Acute sinusitis, LLT: Acute sinusitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Jan 2021 23:14:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Jan 2021 23:14:59
Data point term sent to Coder	System	14 Jan 2021 23:14:03
User entered 'Acute Sinusitis'	Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:13:49

US3892032

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:18:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered 'Yes (Y)'	Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:13:49

US3892032

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:18:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered 'No (N)'	Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:13:49

US3892032

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:18:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered 'No (N)'	Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:13:49

US3892032

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '13 Jan 2021' reason for change: Data Entry Error	(b) (4)	
DataPoint Un-verified.	Andryelle Toledo (b) (4)	17 Feb 2021 16:07:00
	(b) (4)	
User entered '14 Jan 2021' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	17 Feb 2021 16:06:07
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered '11 Jan 2021'	Leslie Iverson (b) (4)	14 Jan 2021 23:13:49
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:18:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered empty.	Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:13:49

US3892032

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:18:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Jan 2021 23:13:49

US3892032

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Un-verified.	Andryelle Toledo (b) (4)	11 Feb 2021 20:34:25
User entered 'No (N)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	11 Feb 2021 20:34:25
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered 'Yes (Y)'	Leslie Iverson (b) (4)	14 Jan 2021 23:13:49

US3892032

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:18:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '22 Jan 2021' reason for change: Data Entry Error	(b) (4)	17 Feb 2021 16:06:07
DataPoint Un-verified.	Andryelle Toledo (b) (4)	11 Feb 2021 20:34:25
User entered '21 Jan 2021' reason for change: Data Entry Error	(b) (4)	11 Feb 2021 20:34:25
DataPoint Verified.	Andryelle Toledo (b) (4)	21 Jan 2021 19:51:04
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 23:13:49

US3892032

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:18:29

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered empty.	Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:13:49

US3892032

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:18:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Jan 2021 23:13:49

US3892032

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:18:29

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Un-verified.	Andryelle Toledo (b) (4)	17 Feb 2021 16:06:07
User entered 'Grade 3/Severe (Grade 3/Severe)'	Andryelle Toledo (b) (4)	17 Feb 2021 16:06:07
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Leslie Iverson (b) (4)	14 Jan 2021 23:13:49

US3892032

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:18:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered 'No (N)'	Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:13:49

US3892032

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:18:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered '0'	Leslie Iverson (b) (4)	14 Jan 2021 23:13:49
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:18:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered '0'	Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:13:49

US3892032

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:18:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered '0'	Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:13:49

US3892032

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:18:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered empty.	Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:13:49

US3892032

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:18:29

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered empty.	Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:13:49

US3892032

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:18:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered empty.	Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:13:49

US3892032

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:18:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered empty.	Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:13:49

US3892032

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:18:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered '0'	Leslie Iverson (b) (4)	14 Jan 2021 23:13:49
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:18:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered '0'	Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:13:49

US3892032

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:18:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered '0'	Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:13:49

US3892032

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:18:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered 'Not Related (NOT RELATED)'	Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:13:49

US3892032

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:18:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered 'Not Related (NOT RELATED)'	Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:13:49

US3892032

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:18:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:13:49

US3892032

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:18:29

None

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered '0'	Leslie Iverson (b) (4)	14 Jan 2021 23:13:49
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered 'I'	Leslie Iverson (b) (4)	14 Jan 2021 23:13:49
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered '0'	Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:13:49

US3892032

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:18:29

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Feb 2021 20:34:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Feb 2021 20:34:25
DataPoint Un-verified.	Andryelle Toledo (b) (4)	11 Feb 2021 20:34:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	11 Feb 2021 20:34:25
Data Entry Error	Andryelle Toledo (b) (4)	11 Feb 2021 20:34:25
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:51:04
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Jan 2021 23:13:49
User entered empty.	Leslie Iverson (b) (4)	14 Jan 2021 23:13:49
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:18:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered empty.	Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:13:49

US3892032

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:18:29

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered empty.	Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:13:49

US3892032

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:18:29

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Jan 2021 23:13:49

US3892032

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:18:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Jan 2021 23:13:49

US3892032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:18:29

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Feb 2021 07:37:26
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 16:24:00
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 16:24:00
Data point term sent to Coder	System	17 Feb 2021 16:08:42
DataPoint Un-verified.	Andryelle Toledo (b) (4) (b) (4)	17 Feb 2021 16:08:03
Coding entries removed.	Andryelle Toledo (b) (4) (b) (4)	17 Feb 2021 16:08:03
User entered 'Nausea' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	17 Feb 2021 16:08:03
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'Yes, I confirm subject was assessed for potential Covid-19 infection' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	16 Feb 2021 17:34:43
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 12:48:53
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:51:04
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Bronchitis, LLT: Acute bronchitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Jan 2021 23:15:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Jan 2021 23:15:58
Data point term sent to Coder	System	14 Jan 2021 23:15:03
User entered 'Acute Bronchitis'	Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:14:52

US3892032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:18:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered 'Yes (Y)'	Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:14:52

US3892032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:18:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered 'No (N)'	Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:14:52

US3892032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:18:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered 'No (N)'	Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:14:52

US3892032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Un-verified.	Andryelle Toledo (b) (4)	17 Feb 2021 16:08:03
User entered '11 Jan 2021' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	17 Feb 2021 16:08:03
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered '13 Jan 2021'	Leslie Iverson (b) (4)	14 Jan 2021 23:14:52

US3892032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:18:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered empty.	Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:14:52

US3892032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:18:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Jan 2021 23:14:52

US3892032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 22:30:43
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	25 Jan 2021 22:30:43
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered 'Yes (Y)'	Leslie Iverson (b) (4)	14 Jan 2021 23:14:52

US3892032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:18:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '13 Jan 2021' reason for change: New Information	Andryelle Toledo (b) (4)	17 Feb 2021 16:08:03
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 22:30:43
User entered '22 Jan 2021' reason for change: New Information	(b) (4), (b) (6)	25 Jan 2021 22:30:43
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered empty.	Leslie Iverson (b) (4)	14 Jan 2021 23:14:52

US3892032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:18:29

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered empty.	Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:14:52

US3892032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:18:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Jan 2021 23:14:52

US3892032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:18:29

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Un-verified.	Andryelle Toledo (b) (4)	17 Feb 2021 16:08:03
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Andryelle Toledo (b) (4)	17 Feb 2021 16:08:03
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered 'Grade 3/Severe (Grade 3/Severe)'	Leslie Iverson (b) (4)	14 Jan 2021 23:14:52

US3892032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:18:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered 'No (N)'	Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:14:52

US3892032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:18:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered '0'	Leslie Iverson (b) (4)	14 Jan 2021 23:14:52
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:18:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered '0'	Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:14:52

US3892032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:18:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered '0'	Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:14:52

US3892032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:18:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered empty.	Leslie Iverson (b) (4)	14 Jan 2021 23:14:52
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:18:29

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered empty.	Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:14:52

US3892032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:18:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered empty.	Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:14:52

US3892032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:18:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered empty.	Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:14:52

US3892032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:18:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered '0'	Leslie Iverson (b) (4)	14 Jan 2021 23:14:52
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:18:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered '0'	Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:14:52

US3892032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:18:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered '0'	Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:14:52

US3892032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:18:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered 'Not Related (NOT RELATED)'	(b) (4) Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:14:52

US3892032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:18:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered 'Not Related (NOT RELATED)'	(b) (4) Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:14:52

US3892032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:18:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:14:52

US3892032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:18:29

None

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 19:51:04
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	14 Jan 2021 23:15:04
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	14 Jan 2021 23:14:52
User entered '0'	Leslie Iverson (b) (4)	14 Jan 2021 23:14:52
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 13:57:12
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'the medication is ZOFRAN' (Site from DM).	Andryelle Toledo (b) (4)	12 Mar 2021 22:16:15
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	12 Mar 2021 04:40:14
DataPoint Verified.	(b) (4)	
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 18:10:34
User entered '0'	(b) (4)	21 Jan 2021 19:51:04
	Leslie Iverson (b) (4)	14 Jan 2021 23:15:04
	(b) (4)	
	Leslie Iverson (b) (4)	14 Jan 2021 23:14:52
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Per DM CLR: Other Action Taken = Con Procedure, However, there is no therapeutic procedure recorded that matches this AE within this timeframe. Diagnostic procedures are not considered treatment. Please review and add procedure as appropriate or update Treatment Required field. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 09:34:00
Query 'Per DM CLR: Other Action Taken = Con Procedure, However, there is no therapeutic procedure recorded that matches this AE within this timeframe. Diagnostic procedures are not considered treatment. Please review and add procedure as appropriate or update Treatment Required field. ' answered with 'update' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	11 Feb 2021 20:37:15
DataPoint Un-verified.	Andryelle Toledo (b) (4) (b) (4)	11 Feb 2021 20:37:09
User entered '0' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	11 Feb 2021 20:37:09
User opened query 'Per DM CLR: Other Action Taken = Con Procedure, However, there is no therapeutic procedure recorded that matches this AE within this timeframe. Diagnostic procedures are not considered treatment. Please review and add procedure as appropriate or update Treatment Required field. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Jan 2021 03:40:21
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered '1' reason for change: Data Entry Error	Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:15:04
User entered '0'	Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:14:52

US3892032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:18:29

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Jan 2021 22:30:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Jan 2021 22:30:43
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 22:30:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	25 Jan 2021 22:30:43
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:51:04
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Jan 2021 23:14:52
User entered empty.	Leslie Iverson (b) (4)	14 Jan 2021 23:14:52
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:18:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered empty.	Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:14:52

US3892032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:18:29

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered empty.	Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:14:52

US3892032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:18:29

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Jan 2021 23:14:52

US3892032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:18:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Jan 2021 23:14:52

US3892032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:18:29

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Feb 2021 07:37:32
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 16:10:01
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 16:10:01
Data point term sent to Coder	System	17 Feb 2021 16:09:42
DataPoint Un-verified.	Andryelle Toledo (b) (4) (b) (4)	17 Feb 2021 16:09:31
Coding entries removed.	Andryelle Toledo (b) (4) (b) (4)	17 Feb 2021 16:09:31
User entered 'Fatigue' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	17 Feb 2021 16:09:31
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'Yes, I confirm subject was assessed for potential Covid-19 infection' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	16 Feb 2021 17:34:53
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 12:49:10
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:51:04
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Jan 2021 22:50:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Jan 2021 22:50:00
Data point term sent to Coder	System	15 Jan 2021 22:48:28
User entered 'Nausea'	Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 22:47:58

US3892032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:18:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Un-verified.	Andryelle Toledo (b) (4)	17 Feb 2021 16:09:31
User entered 'No (N)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	17 Feb 2021 16:09:31
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Leslie Iverson (b) (4)	15 Jan 2021 22:49:47
User entered 'No (N)'	Leslie Iverson (b) (4)	15 Jan 2021 22:47:58

US3892032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:18:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Un-verified.	Andryelle Toledo (b) (4)	17 Feb 2021 16:09:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	17 Feb 2021 16:09:31
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered 'No (N)'	Leslie Iverson (b) (4)	15 Jan 2021 22:47:58

US3892032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:18:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered 'No (N)'	Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 22:47:58

US3892032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Un-verified.	Andryelle Toledo (b) (4)	17 Feb 2021 16:09:31
User entered '31 Aug 2020' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	17 Feb 2021 16:09:31
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered '11 Jan 2021'	Leslie Iverson (b) (4)	15 Jan 2021 22:47:58

US3892032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:18:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Un-verified.	Andryelle Toledo (b) (4)	17 Feb 2021 16:09:31
User entered '19:51' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	17 Feb 2021 16:09:31
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 22:47:58

US3892032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:18:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 19:51'	System	17 Feb 2021 16:09:31
User entered empty.	System	15 Jan 2021 22:47:58

US3892032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Un-verified.	Andryelle Toledo (b) (4)	11 Feb 2021 20:34:49
User entered 'No (N)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	11 Feb 2021 20:34:49
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered 'Yes (Y)'	Leslie Iverson (b) (4)	15 Jan 2021 22:47:58

US3892032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:18:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4)	17 Feb 2021 16:09:31
DataPoint Un-verified.	Andryelle Toledo (b) (4)	11 Feb 2021 20:34:49
User entered '13 Jan 2021' reason for change: Data Entry Error	(b) (4)	11 Feb 2021 20:34:49
DataPoint Verified.	Andryelle Toledo (b) (4)	21 Jan 2021 19:51:04
User entered empty.	(b) (4), (b) (6)	15 Jan 2021 22:47:58
	Leslie Iverson (b) (4)	
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:18:29

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	18 Feb 2021 07:39:21
Query 'Data is required. Please provide.' answered with 'Time is UNK' (Site from System).	Andryelle Toledo (b) (4) (b) (4)	17 Feb 2021 16:09:48
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Feb 2021 16:09:31
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered empty.	Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 22:47:58

US3892032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:18:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Jan 2021 22:47:58

US3892032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:18:29

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 22:47:58

US3892032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:18:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered 'No (N)'	Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 22:47:58

US3892032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:18:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered '0'	(b) (4)	
	Leslie Iverson (b) (4)	15 Jan 2021 22:47:58
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:18:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered '0'	Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 22:47:58

US3892032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:18:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered '0'	Leslie Iverson (b) (4)	15 Jan 2021 22:47:58
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:18:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered empty.	Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 22:47:58

US3892032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:18:29

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered empty.	Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 22:47:58

US3892032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:18:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered empty.	Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 22:47:58

US3892032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:18:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered empty.	Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 22:47:58

US3892032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:18:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered '0'	Leslie Iverson (b) (4)	15 Jan 2021 22:47:58
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:18:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered '0'	Leslie Iverson (b) (4)	15 Jan 2021 22:47:58
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:18:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered '0'	Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 22:47:58

US3892032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:18:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Un-verified.	Andryelle Toledo (b) (4)	17 Feb 2021 16:09:31
User entered 'Related (RELATED)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	17 Feb 2021 16:09:31
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered 'Not Related (NOT RELATED)'	Leslie Iverson (b) (4)	15 Jan 2021 22:47:58

US3892032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:18:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered 'Not Related (NOT RELATED)'	(b) (4) Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 22:47:58

US3892032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:18:29

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 17:51:36
Query 'Per Sponsor Review, per CDM: Please consider updating 'Action taken with investigational product' to None' answered with 'Update' (Site from DM).	Andryelle Toledo (b) (4)	03 May 2021 14:08:47
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	03 May 2021 14:08:26
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per Sponsor Review, per CDM: Please consider updating 'Action taken with investigational product' to None' (Site from DM).	Andryelle Toledo (b) (4)	03 May 2021 14:08:26
User signature succeeded.	(b) (4)	
	(b) (4), (b) (6)	30 Apr 2021 02:12:41
	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered 'Not Applicable (NOT APPLICABLE)'	Leslie Iverson (b) (4)	15 Jan 2021 22:47:58
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:18:29

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Un-verified.	Andryelle Toledo (b) (4)	17 Feb 2021 16:09:31
User entered '1' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	17 Feb 2021 16:09:31
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered '0'	Leslie Iverson (b) (4)	15 Jan 2021 22:47:58

US3892032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Un-verified.	Andryelle Toledo (b) (4)	17 Feb 2021 16:09:31
User entered '0' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	17 Feb 2021 16:09:31
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered '1'	Leslie Iverson (b) (4)	15 Jan 2021 22:47:58

US3892032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered '0'	Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 22:47:58

US3892032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:18:29

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Feb 2021 20:34:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Feb 2021 20:34:49
DataPoint Un-verified.	Andryelle Toledo (b) (4)	11 Feb 2021 20:34:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	11 Feb 2021 20:34:49
Data Entry Error	Andryelle Toledo (b) (4)	11 Feb 2021 20:34:49
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:51:04
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Jan 2021 22:47:58
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 22:47:58
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:18:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered empty.	Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 22:47:58

US3892032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:18:29

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Un-verified.	Andryelle Toledo (b) (4)	17 Feb 2021 16:11:57
User entered 'Symptom initially captured as solicited adverse event in diary only but required AE page/event due to still ongoing after day 7. It also overlapped AE of allergies to wildfire smoke, but is considered to be solicited AE likely related to vaccine as it persisted longer than symptoms for AE # 1.' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	17 Feb 2021 16:11:57
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:51:04
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 22:47:58

US3892032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:18:29

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	15 Jan 2021 22:47:58

US3892032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:18:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Feb 2021 16:09:31
User entered '1'	System	15 Jan 2021 22:49:47
User entered '0'	System	15 Jan 2021 22:47:58

US3892032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:18:29

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 16:35:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 16:35:59
Data point term sent to Coder	System	24 Feb 2021 16:35:01
User entered 'Headache'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:34:28

US3892032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:18:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:34:28

US3892032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:18:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:34:28

US3892032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:18:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:34:28

US3892032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '29 Sep 2020'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:34:28

US3892032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:18:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	26 Feb 2021 13:00:18
Query 'Data is required. Please provide.' answered with 'Time is UNK' (Site from System).	Andryelle Toledo (b) (4)	24 Feb 2021 16:34:38
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Feb 2021 16:34:28
User entered empty.	Andryelle Toledo (b) (4)	24 Feb 2021 16:34:28
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:18:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 16:34:28

US3892032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:34:28

US3892032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:18:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '11 Oct 2020'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:34:28

US3892032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:18:29

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	26 Feb 2021 13:00:20
Query 'Data is required. Please provide.' answered with 'Time is UNK' (Site from System).	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:34:42
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Feb 2021 16:34:28
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:34:28

US3892032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:18:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 16:34:28

US3892032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:18:29

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:34:28

US3892032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:18:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:34:28

US3892032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:18:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4)	24 Feb 2021 16:34:28
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:18:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:34:28

US3892032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:18:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:34:28

US3892032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:18:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:34:28

US3892032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:18:29

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:34:28

US3892032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:18:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:34:28

US3892032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:18:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:34:28

US3892032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:18:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:34:28

US3892032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:18:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:34:28

US3892032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:18:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:34:28

US3892032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:18:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'Related (RELATED)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:34:28

US3892032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:18:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'Not Related (NOT RELATED)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:34:28

US3892032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:18:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'Not Applicable (NOT APPLICABLE)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:34:28

US3892032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:18:29

None

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:34:28

US3892032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
User closed query 'Per CDM: RE-QUERY: Per response symptom HEADACHE was included within the AE of Viral Syndrome. However, since HEADACHE is recorded as separate AE, please consider recording in concomitant medication page if it is appropriate. Thank you.' (Site from DM). Query 'Per CDM: RE-QUERY: Per response symptom HEADACHE was included within the AE of Viral Syndrome. However, since HEADACHE is recorded as separate AE, please consider recording in concomitant medication page if it is appropriate. Thank you.' answered with 'Update medical indication for conc. medication # 11' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 05:45:21
User opened query 'Per CDM: RE-QUERY: Per response symptom HEADACHE was included within the AE of Viral Syndrome. However, since HEADACHE is recorded as separate AE, please consider recording in concomitant medication page if it is appropriate. Thank you.'	Andryelle Toledo (b) (4) (b) (4)	05 Mar 2021 16:47:11
User closed query 'Per CDM: RE-QUERY: Per response symptom HEADACHE was included within the AE of Viral Syndrome. However, since HEADACHE is recorded as separate AE, please consider recording in concomitant medication page if it is appropriate. Thank you.'	(b) (4), (b) (6)	05 Mar 2021 07:11:31
User opened query 'Per CDM: RE-QUERY: Per response symptom HEADACHE was included within the AE of Viral Syndrome. However, since HEADACHE is recorded as separate AE, please consider recording in concomitant medication page if it is appropriate. Thank you.'	(b) (4), (b) (6)	05 Mar 2021 07:08:49
User closed query 'Per CDM: Concomitant Medication is checked Yes, however, there is no corresponding medication recorded on the Prior and Concomitant Medications form with an Indication of HEADACHE. Please clarify and update as appropriate.' (Site from DM). Query 'Per CDM: Concomitant Medication is checked Yes, however, there is no corresponding medication recorded on the Prior and Concomitant Medications form with an Indication of HEADACHE. Please clarify and update as appropriate.' answered with ' This symptom was reported in the eDiary, however it is included within the AE of Viral Syndrome that occurred during the same period. Can you please instruct me if I should put more than one indication within the same medication. The related medication is number 11.' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	04 Mar 2021 16:07:38

US3892032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Concomitant Medication is checked Yes, however, there is no corresponding medication recorded on the Prior and Concomitant Medications form with an Indication of HEADACHE. Please clarify and update as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 11:38:10
	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'I'	Andryelle Toledo (b) (4)	24 Feb 2021 16:34:28
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:34:28

US3892032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:18:29

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:34:28

US3892032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:18:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:34:28

US3892032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:18:29

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:34:28

US3892032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:18:29

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	24 Feb 2021 16:34:28

US3892032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:18:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Feb 2021 16:34:28

US3892032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:18:29

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	24 Feb 2021 16:36:59
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Feb 2021 16:36:59
	(b) (4)	
Data point term sent to Coder	System	24 Feb 2021 16:36:02
User entered 'Fatigue'	Andryelle Toledo (b) (4)	24 Feb 2021 16:35:56
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:18:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:35:56

US3892032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:18:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:35:56

US3892032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:18:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:35:56

US3892032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '29 Sep 2020'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:35:56

US3892032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:18:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	26 Feb 2021 13:00:39
Query 'Data is required. Please provide.' answered with 'Time is UNK' (Site from System).	Andryelle Toledo (b) (4)	24 Feb 2021 16:36:02
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Feb 2021 16:35:56
User entered empty.	Andryelle Toledo (b) (4)	24 Feb 2021 16:35:56
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:18:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 16:35:56

US3892032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:35:56

US3892032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:18:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '12 Oct 2020'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:35:56

US3892032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:18:29

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	26 Feb 2021 13:00:42
Query 'Data is required. Please provide.' answered with 'Time is UNK' (Site from System).	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:36:06
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Feb 2021 16:35:56
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:35:56

US3892032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:18:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 16:35:56

US3892032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:18:29

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'Grade 3/Severe (Grade 3/Severe)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:35:56

US3892032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:18:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:35:56

US3892032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:18:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:35:56

US3892032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:18:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:35:56

US3892032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:18:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:35:56

US3892032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:18:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:35:56

US3892032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:18:29

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:35:56

US3892032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:18:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:35:56

US3892032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:18:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:35:56

US3892032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:18:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:35:56

US3892032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:18:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:35:56

US3892032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:18:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:35:56

US3892032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:18:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'Related (RELATED)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:35:56

US3892032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:18:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'Not Related (NOT RELATED)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:35:56

US3892032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:18:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'Not Applicable (NOT APPLICABLE)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:35:56

US3892032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:18:29

None

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'I'	Andryelle Toledo (b) (4)	24 Feb 2021 16:35:56
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:35:56

US3892032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:35:56

US3892032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:18:29

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:35:56

US3892032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:18:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:35:56

US3892032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:18:29

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:35:56

US3892032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:18:29

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	24 Feb 2021 16:35:56

US3892032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:18:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Feb 2021 16:35:56

US3892032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:18:29

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 20:26:35
User closed query 'Per DM CLR: Please provide the specific location of muscle pain (eg, generalized myalgia, back muscle pain, arms, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 13:23:51
Query 'Per DM CLR: Please provide the specific location of muscle pain (eg, generalized myalgia, back muscle pain, arms, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'update' (Site from DM).	Andryelle Toledo (b) (4)	23 Mar 2021 15:01:28
	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Myalgia - version MedDRA\23.0.	Coder Import (b) (4)	23 Mar 2021 15:00:37
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Mar 2021 15:00:37
	(b) (4)	
Data point term sent to Coder	System	23 Mar 2021 14:59:56
DataPoint Un-verified.	Andryelle Toledo (b) (4)	23 Mar 2021 14:59:30
	(b) (4)	
Coding entries removed.	Andryelle Toledo (b) (4)	23 Mar 2021 14:59:30
	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	23 Mar 2021 14:59:30
	(b) (4)	
User entered 'Generalized MYALGIA' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	23 Mar 2021 14:59:30
	(b) (4)	
User opened query 'Per DM CLR: Please provide the specific location of muscle pain (eg, generalized myalgia, back muscle pain, arms, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 06:46:17
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17

US3892032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:18:29

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Myalgia - version MedDRA\\23.0.	Coder Import (b) (4)	24 Feb 2021 16:41:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	24 Feb 2021 16:41:04
Data point term sent to Coder	System	24 Feb 2021 16:40:09
User entered 'Myalgia'	Andryelle Toledo (b) (4)	24 Feb 2021 16:39:17
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:18:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:39:17

US3892032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:18:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:39:17

US3892032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:18:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:39:17

US3892032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '29 Sep 2020'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:39:17

US3892032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:18:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	26 Feb 2021 13:01:59
Query 'Data is required. Please provide.' answered with 'Time is UNK' (Site from System).	Andryelle Toledo (b) (4)	24 Feb 2021 16:39:36
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Feb 2021 16:39:17
User entered empty.	Andryelle Toledo (b) (4)	24 Feb 2021 16:39:17
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:18:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 16:39:17

US3892032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:39:17

US3892032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:18:29

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '09 Oct 2020'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:39:17

US3892032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:18:29

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	26 Feb 2021 13:02:01
Query 'Data is required. Please provide.' answered with 'Time is UNK' (Site from System).	Andryelle Toledo (b) (4)	24 Feb 2021 16:39:59
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Feb 2021 16:39:17
User entered empty.	Andryelle Toledo (b) (4)	24 Feb 2021 16:39:17
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:18:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 16:39:17

US3892032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:18:29

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'Grade 3/Severe (Grade 3/Severe)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:39:17

US3892032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:18:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:39:17

US3892032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:18:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:39:17

US3892032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:18:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:39:17

US3892032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:18:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:39:17

US3892032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:18:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:39:17

US3892032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:18:29

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:39:17

US3892032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:18:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:39:17

US3892032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:18:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:39:17

US3892032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:18:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:39:17

US3892032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:18:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:39:17

US3892032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:18:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:39:17

US3892032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:18:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'Related (RELATED)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:39:17

US3892032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:18:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'Not Related (NOT RELATED)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:39:17

US3892032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:18:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'Not Applicable (NOT APPLICABLE)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:39:17

US3892032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:18:29

None

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:39:17

US3892032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
User closed query 'PER CDM: RE-QUERY: Per response 'Update medical indication for conc. medication # 11'. However, MYALGIA is not recorded as indication for conmed # 11. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 06:56:07
Query 'PER CDM: RE-QUERY: Per response 'Update medical indication for conc. medication # 11'. However, MYALGIA is not recorded as indication for conmed # 11. Please review and update as appropriate. Thank you.' answered with 'I updated. The conc. medication related is number 21. Thank you.' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	09 Mar 2021 19:53:03
User opened query 'PER CDM: RE-QUERY: Per response 'Update medical indication for conc. medication # 11'. However, MYALGIA is not recorded as indication for conmed # 11. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 05:47:12
User closed query 'Per CDM: RE-QUERY: Per response symptom MYALGIA was included within the AE of Viral Syndrome. However, since MYALGIA is recorded as separate AE, please consider recording in concomitant medication page if it is appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 05:47:12
Query 'Per CDM: RE-QUERY: Per response symptom MYALGIA was included within the AE of Viral Syndrome. However, since MYALGIA is recorded as separate AE, please consider recording in concomitant medication page if it is appropriate. Thank you.' answered with 'Update medical indication for conc. medication # 11' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	05 Mar 2021 16:47:25
User opened query 'Per CDM: RE-QUERY: Per response symptom MYALGIA was included within the AE of Viral Syndrome. However, since MYALGIA is recorded as separate AE, please consider recording in concomitant medication page if it is appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 07:16:24

US3892032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
Query 'Per CDM: RE-QUERY: Per response symptom HEADACHE was included within the AE of Viral Syndrome. However, since MYALGIA is recorded as separate AE, please consider recording in concomitant medication page if it is appropriate. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 07:16:09
User opened query 'Per CDM: RE-QUERY: Per response symptom HEADACHE was included within the AE of Viral Syndrome. However, since MYALGIA is recorded as separate AE, please consider recording in concomitant medication page if it is appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 07:16:00
User closed query 'Per CDM: Concomitant Medication is checked Yes, however, there is no corresponding medication recorded on the Prior and Concomitant Medications form with an Indication of MYLGIA. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 07:16:00
Query 'Per CDM: Concomitant Medication is checked Yes, however, there is no corresponding medication recorded on the Prior and Concomitant Medications form with an Indication of MYLGIA. Please clarify and update as appropriate.' answered with 'This symptom was reported in the eDiary, however it is included within the AE of Viral Syndrome that occurred during the same period. Can you please instruct me if I should put more than one indication within the same medication. The related medication is number 11.' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	04 Mar 2021 16:08:00
User opened query 'Per CDM: Concomitant Medication is checked Yes, however, there is no corresponding medication recorded on the Prior and Concomitant Medications form with an Indication of MYLGIA. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 11:39:20
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '1'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:39:17

US3892032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4)	24 Feb 2021 16:39:17
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:18:29

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:39:17

US3892032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:18:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:39:17

US3892032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:18:29

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:39:17

US3892032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:18:29

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	24 Feb 2021 16:39:17

US3892032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:18:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Feb 2021 16:39:17

US3892032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:18:29

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 20:26:35
User closed query 'Per DM CLR: Please provide the specific location of joint pain (eg, generalized arthralgia knee joint pain, shoulder joint pain, etc.) Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 13:24:27
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Arthralgia - version MedDRA\23.0.	Coder Import (b) (4)	23 Mar 2021 15:05:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	23 Mar 2021 15:05:36
Data point term sent to Coder	System	23 Mar 2021 15:05:01
Query 'Per DM CLR: Please provide the specific location of joint pain (eg, generalized arthralgia knee joint pain, shoulder joint pain, etc.) Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'update' (Site from DM).	Andryelle Toledo (b) (4)	23 Mar 2021 15:04:35
DataPoint Un-verified.	(b) (4)	
	Andryelle Toledo (b) (4)	23 Mar 2021 15:04:28
Coding entries removed.	(b) (4)	
	Andryelle Toledo (b) (4)	23 Mar 2021 15:04:28
Signature has been broken.	(b) (4)	
	Andryelle Toledo (b) (4)	23 Mar 2021 15:04:28
User entered 'Generalized ARTHRALGIA' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	23 Mar 2021 15:04:28
User opened query 'Per DM CLR: Please provide the specific location of joint pain (eg, generalized arthralgia knee joint pain, shoulder joint pain, etc.) Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 06:46:34
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
	(b) (4)	

PRODUCTION RELEASE (v12.003
EAB) (1725)

3687 of 4365

US3892032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:18:29

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Arthralgia - version MedDRA\\23.0.	Coder Import (b) (4)	24 Feb 2021 16:43:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	24 Feb 2021 16:43:59
Data point term sent to Coder	System	24 Feb 2021 16:43:17
User entered 'Arthralgia'	Andryelle Toledo (b) (4)	24 Feb 2021 16:42:21
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:18:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:42:21

US3892032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:18:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:42:21

US3892032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:18:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:42:21

US3892032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '29 Sep 2020'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:42:21

US3892032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:18:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	26 Feb 2021 13:02:12
Query 'Data is required. Please provide.' answered with 'Time is UNK' (Site from System).	Andryelle Toledo (b) (4)	24 Feb 2021 16:42:28
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Feb 2021 16:42:21
User entered empty.	Andryelle Toledo (b) (4)	24 Feb 2021 16:42:21
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:18:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 16:42:21

US3892032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:42:21

US3892032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:18:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '10 Oct 2020'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:42:21

US3892032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:18:29

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	26 Feb 2021 13:02:15
Query 'Data is required. Please provide.' answered with 'Time is UNK' (Site from System).	Andryelle Toledo (b) (4)	24 Feb 2021 16:42:31
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Feb 2021 16:42:21
User entered empty.	Andryelle Toledo (b) (4)	24 Feb 2021 16:42:21
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:18:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 16:42:21

US3892032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:18:29

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'Grade 3/Severe (Grade 3/Severe)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:42:21

US3892032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:18:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:42:21

US3892032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:18:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:42:21

US3892032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:18:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:42:21

US3892032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:18:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:42:21

US3892032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:18:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:42:21

US3892032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:18:29

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:42:21

US3892032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:18:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:42:21

US3892032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:18:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:42:21

US3892032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:18:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:42:21

US3892032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:18:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:42:21

US3892032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:18:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:42:21

US3892032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:18:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'Related (RELATED)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:42:21

US3892032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:18:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'Not Related (NOT RELATED)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:42:21

US3892032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:18:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'Not Applicable (NOT APPLICABLE)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:42:21

US3892032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:18:29

None

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4)	24 Feb 2021 16:42:21
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
User closed query 'PER CDM: RE-QUERY: Per response 'Update medical indication for conc. medication # 11'. However, ARTHRALGIA is not recorded as indication for conmed # 11. Please review and update as appropriate. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 06:56:18
Query 'PER CDM: RE-QUERY: Per response 'Update medical indication for conc. medication # 11'. However, ARTHRALGIA is not recorded as indication for conmed # 11. Please review and update as appropriate. Thank you' answered with 'I updated. The conc. medication related is number 21. Thank you.' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	09 Mar 2021 19:53:14
User opened query 'PER CDM: RE-QUERY: Per response 'Update medical indication for conc. medication # 11'. However, ARTHRALGIA is not recorded as indication for conmed # 11. Please review and update as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 05:47:40
User closed query 'Per CDM: RE-QUERY: Per response symptom ARTHRALGIA was included within the AE of Viral Syndrome. However, since ARTHRALGIA is recorded as separate AE, please consider recording in concomitant medication page if it is appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 05:47:40
Query 'Per CDM: RE-QUERY: Per response symptom ARTHRALGIA was included within the AE of Viral Syndrome. However, since ARTHRALGIA is recorded as separate AE, please consider recording in concomitant medication page if it is appropriate. Thank you' answered with 'Update medical indication for conc. medication # 11' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	05 Mar 2021 16:47:35
User opened query 'Per CDM: RE-QUERY: Per response symptom ARTHRALGIA was included within the AE of Viral Syndrome. However, since ARTHRALGIA is recorded as separate AE, please consider recording in concomitant medication page if it is appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 07:18:07

US3892032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Concomitant Medication is checked Yes, however, there is no corresponding medication recorded on the Prior and Concomitant Medications form with an Indication of ARTHRALGIA. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 07:18:07
Query 'Per CDM: Concomitant Medication is checked Yes, however, there is no corresponding medication recorded on the Prior and Concomitant Medications form with an Indication of ARTHRALGIA. Please clarify and update as appropriate.' answered with 'This symptom was reported in the eDiary, however it is included within the AE of Viral Syndrome that occurred during the same period. Can you please instruct me if I should put more than one indication within the same medication. The related medication is number 11.' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	04 Mar 2021 16:08:09
User opened query 'Per CDM: Concomitant Medication is checked Yes, however, there is no corresponding medication recorded on the Prior and Concomitant Medications form with an Indication of ARTHRALGIA. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 11:41:04
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'I'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:42:21

US3892032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:42:21

US3892032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:18:29

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 16:42:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Feb 2021 16:42:40
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Andryelle Toledo (b) (4)	24 Feb 2021 16:42:40
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 16:42:21
User entered empty.	Andryelle Toledo (b) (4)	24 Feb 2021 16:42:21
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:18:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:42:21

US3892032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:18:29

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:42:21

US3892032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:18:29

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	24 Feb 2021 16:42:21

US3892032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:18:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Feb 2021 16:42:21

US3892032

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:18:29

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Feelings and sensations NEC, PT: Chills, LLT: Chills - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 16:59:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 16:59:58
Data point term sent to Coder	System	24 Feb 2021 16:44:19
User entered 'Chills'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:43:49

US3892032

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:18:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:43:49

US3892032

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:18:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:43:49

US3892032

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:18:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:43:49

US3892032

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '29 Sep 2020'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:43:49

US3892032

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:18:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	26 Feb 2021 13:03:23
Query 'Data is required. Please provide.' answered with 'Time is UNK' (Site from System).	Andryelle Toledo (b) (4)	24 Feb 2021 16:44:36
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Feb 2021 16:43:49
User entered empty.	Andryelle Toledo (b) (4)	24 Feb 2021 16:43:49
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:18:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 16:43:49

US3892032

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:43:49

US3892032

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:18:29

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '06 Oct 2020'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:43:49

US3892032

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:18:29

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	26 Feb 2021 13:03:25
Query 'Data is required. Please provide.' answered with 'Time is UNK' (Site from System).	Andryelle Toledo (b) (4)	24 Feb 2021 16:44:39
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Feb 2021 16:43:49
User entered empty.	Andryelle Toledo (b) (4)	24 Feb 2021 16:43:49
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:18:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 16:43:49

US3892032

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:18:29

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:43:49

US3892032

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:18:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:43:49

US3892032

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:18:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:43:49

US3892032

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:18:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:43:49

US3892032

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:18:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:43:49

US3892032

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:18:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:43:49

US3892032

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:18:29

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:43:49

US3892032

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:18:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:43:49

US3892032

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:18:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:43:49

US3892032

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:18:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:43:49

US3892032

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:18:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:43:49

US3892032

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:18:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:43:49

US3892032

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:18:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'Related (RELATED)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:43:49

US3892032

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:18:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'Not Related (NOT RELATED)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:43:49

US3892032

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:18:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'Not Applicable (NOT APPLICABLE)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:43:49

US3892032

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:18:29

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'I'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:43:49

US3892032

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:43:49

US3892032

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:43:49

US3892032

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:18:29

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:43:49

US3892032

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:18:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:43:49

US3892032

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:18:29

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:43:49

US3892032

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:18:29

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Feb 2021 16:43:49

US3892032

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:18:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Feb 2021 16:43:49

US3892032

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:18:29

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 20:25:07
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4)	30 Mar 2021 17:23:12
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	30 Mar 2021 17:23:12
	(b) (4)	
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4)	30 Mar 2021 17:22:11
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	30 Mar 2021 17:22:11
	(b) (4)	
Data point term sent to Coder	System	30 Mar 2021 17:21:57
User closed query 'For coding purposes, please split NAUSEA/VOMITING into separate entries. 1. NAUSEA and 2. VOMITING' (Site from System).	System	30 Mar 2021 17:21:14
Query 'For coding purposes, please split NAUSEA/VOMITING into separate entries. 1. NAUSEA and 2. VOMITING' answered with 'update' (Site from System).	Andryelle Toledo (b) (4)	30 Mar 2021 17:21:14
	(b) (4)	
Data point term sent to Coder	System	30 Mar 2021 17:20:56
DataPoint Un-verified.	Andryelle Toledo (b) (4)	30 Mar 2021 17:20:17
	(b) (4)	
Coding entries removed.	Andryelle Toledo (b) (4)	30 Mar 2021 17:20:17
	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	30 Mar 2021 17:20:17
	(b) (4)	
User entered 'NAUSEA' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	30 Mar 2021 17:20:17
	(b) (4)	
User opened query 'For coding purposes, please split NAUSEA/VOMITING into separate entries. 1. NAUSEA and 2. VOMITING' (Site from System).	Coder Import (b) (4)	28 Mar 2021 13:30:22
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:17

US3892032

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:18:29

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\\23.0.	Coder Import (b) (4)	24 Feb 2021 16:46:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Feb 2021 16:46:59
Data point term sent to Coder	System	24 Feb 2021 16:46:21
User entered 'Nausea/Vomiting'	Andryelle Toledo (b) (4)	24 Feb 2021 16:45:25
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:18:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:45:25

US3892032

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:18:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:45:25

US3892032

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:18:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:45:25

US3892032

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '29 Sep 2020'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:45:25

US3892032

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:18:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	26 Feb 2021 13:03:41
Query 'Data is required. Please provide.' answered with 'Time is UNK' (Site from System).	Andryelle Toledo (b) (4)	24 Feb 2021 16:45:38
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Feb 2021 16:45:25
User entered empty.	Andryelle Toledo (b) (4)	24 Feb 2021 16:45:25
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:18:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 16:45:25

US3892032

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:45:25

US3892032

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:18:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '11 Oct 2020'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:45:25

US3892032

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:18:29

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	26 Feb 2021 13:03:44
Query 'Data is required. Please provide.' answered with 'Time is UNK' (Site from System).	Andryelle Toledo (b) (4)	24 Feb 2021 16:45:45
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Feb 2021 16:45:25
User entered empty.	Andryelle Toledo (b) (4)	24 Feb 2021 16:45:25
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:18:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 16:45:25

US3892032

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:18:29

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:45:25

US3892032

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:18:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:45:25

US3892032

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:18:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:45:25

US3892032

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:18:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:45:25

US3892032

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:18:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:45:25

US3892032

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:18:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:45:25

US3892032

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:18:29

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:45:25

US3892032

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:18:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:45:25

US3892032

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:18:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:45:25

US3892032

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:18:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4)	24 Feb 2021 16:45:25
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:18:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:45:25

US3892032

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:18:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4)	24 Feb 2021 16:45:25
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:18:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'Related (RELATED)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:45:25

US3892032

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:18:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'Not Related (NOT RELATED)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:45:25

US3892032

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:18:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'Not Applicable (NOT APPLICABLE)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:45:25

US3892032

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:18:29

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'I'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:45:25

US3892032

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:45:25

US3892032

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered '0'	Andryelle Toledo (b) (4)	24 Feb 2021 16:45:25
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:18:29

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:45:25

US3892032

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:18:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:45:25

US3892032

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:18:29

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:17
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 16:45:25

US3892032

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:18:29

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	24 Feb 2021 16:45:25

US3892032

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:18:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Feb 2021 16:45:25

US3892032

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:18:29

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 20:25:14
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\\23.0.	Coder Import (b) (4)	30 Mar 2021 17:25:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Mar 2021 17:25:02
Data point term sent to Coder	System	30 Mar 2021 17:23:59
User entered 'Vomiting'	Andryelle Toledo (b) (4)	30 Mar 2021 17:23:37
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:18:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:25:16
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	30 Mar 2021 17:23:37

US3892032

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:18:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:25:19
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	30 Mar 2021 17:23:37

US3892032

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:18:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:25:21
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	30 Mar 2021 17:23:37

US3892032

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:25:23
User entered '29 Sep 2020'	Andryelle Toledo (b) (4) (b) (4)	30 Mar 2021 17:23:37

US3892032

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:18:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	31 Mar 2021 09:42:58
DataPoint Verified.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	30 Mar 2021 20:25:25
Query 'Data is required. Please provide.' answered with 'time is unk' (Site from System).	Andryelle Toledo (b) (4)	30 Mar 2021 17:23:50
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	
User entered empty.	System	30 Mar 2021 17:23:37
	Andryelle Toledo (b) (4)	30 Mar 2021 17:23:37
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:18:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 17:23:37

US3892032

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:25:28
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	30 Mar 2021 17:23:37

US3892032

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:18:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 20:25:31
User entered '11 Oct 2020'	Andryelle Toledo (b) (4)	30 Mar 2021 17:23:37
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:18:29

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 09:43:00
	(b) (4), (b) (6)	30 Mar 2021 20:25:32
Query 'Data is required. Please provide.' answered with 'time is unk' (Site from System).	Andryelle Toledo (b) (4)	30 Mar 2021 17:23:54
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	
User entered empty.	System	30 Mar 2021 17:23:37
	Andryelle Toledo (b) (4)	30 Mar 2021 17:23:37
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:18:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 17:23:37

US3892032

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:18:29

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:25:34
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Andryelle Toledo (b) (4) (b) (4)	30 Mar 2021 17:23:37

US3892032

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:18:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:25:36
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	30 Mar 2021 17:23:37

US3892032

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:18:29

Death

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 20:25:38
User entered '0'	Andryelle Toledo (b) (4)	30 Mar 2021 17:23:37
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:18:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 20:25:40
User entered '0'	Andryelle Toledo (b) (4)	30 Mar 2021 17:23:37
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:18:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:25:42
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	30 Mar 2021 17:23:37

US3892032

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:18:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:25:44
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	30 Mar 2021 17:23:37

US3892032

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:18:29

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:25:45
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	30 Mar 2021 17:23:37

US3892032

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:18:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:25:48
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	30 Mar 2021 17:23:37

US3892032

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:18:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:25:52
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	30 Mar 2021 17:23:37

US3892032

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:18:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:25:54
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	30 Mar 2021 17:23:37

US3892032

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:18:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:25:56
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	30 Mar 2021 17:23:37

US3892032

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:18:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:25:58
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	30 Mar 2021 17:23:37

US3892032

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:18:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:26:00
User entered 'Related (RELATED)'	Andryelle Toledo (b) (4) (b) (4)	30 Mar 2021 17:23:37

US3892032

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:18:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:26:02
User entered 'Not Related (NOT RELATED)'	Andryelle Toledo (b) (4) (b) (4)	30 Mar 2021 17:23:37

US3892032

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:18:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:26:04
User entered 'Not Applicable (NOT APPLICABLE)'	Andryelle Toledo (b) (4) (b) (4)	30 Mar 2021 17:23:37

US3892032

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:18:29

None

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 20:26:06
User entered 'I'	Andryelle Toledo (b) (4)	30 Mar 2021 17:23:37
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 20:26:08
User entered '0'	Andryelle Toledo (b) (4)	30 Mar 2021 17:23:37
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:26:10
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	30 Mar 2021 17:23:37

US3892032

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:18:29

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:26:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Andryelle Toledo (b) (4) (b) (4)	30 Mar 2021 17:23:37

US3892032

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:18:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:26:13
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	30 Mar 2021 17:23:37

US3892032

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:18:29

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:26:15
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	30 Mar 2021 17:23:37

US3892032

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:18:29

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	30 Mar 2021 17:23:37

US3892032

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 10:18:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Mar 2021 17:23:37

US3892032

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:18:29

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:55:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Meniscus injury, LLT: Meniscus tear of knee - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 17:27:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 17:27:19
Data point term sent to Coder	System	06 Apr 2021 17:26:21
User entered 'Meniscus tear Left knee'	Andryelle Toledo (b) (4)	06 Apr 2021 17:25:35

US3892032

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:18:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:55:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	06 Apr 2021 17:25:35

US3892032

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:18:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:55:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	06 Apr 2021 17:25:35

US3892032

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:18:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:55:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	06 Apr 2021 17:25:35

US3892032

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:18:29

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:55:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered '22 Mar 2021'	(b) (4) Andryelle Toledo (b) (4)	06 Apr 2021 17:25:35

US3892032

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:18:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:55:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	06 Apr 2021 17:25:35

US3892032

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:18:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 17:25:35

US3892032

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please verify If AE #18 "Meniscus tear left kneww" has start date = 22MAR2021 and is marked as "Ongoing" = Yes, kindly confirm if the AE is still ongoing. Thanks' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 08:32:48
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:55:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
Query 'Per CDM: Please verify If AE #18 "Meniscus tear left kneww" has start date = 22MAR2021 and is marked as "Ongoing" = Yes, kindly confirm if the AE is still ongoing. Thanks' answered with 'Confirm' (Site from DM).	Andryelle Toledo (b) (4)	12 Apr 2021 14:37:25
User opened query 'Per CDM: Please verify If AE #18 "Meniscus tear left kneww" has start date = 22MAR2021 and is marked as "Ongoing" = Yes, kindly confirm if the AE is still ongoing. Thanks' (Site from DM).	(b) (4), (b) (6)	10 Apr 2021 07:23:57
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	06 Apr 2021 17:25:35

US3892032

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:18:29

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:55:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered empty.	Andryelle Toledo (b) (4)	06 Apr 2021 17:25:35

US3892032

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:18:29

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:55:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	06 Apr 2021 17:25:35

US3892032

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:18:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 17:25:35

US3892032

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:18:29

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:55:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Andryelle Toledo (b) (4)	06 Apr 2021 17:25:35

US3892032

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:18:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:55:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered 'No (N)'	Andryelle Toledo (b) (4)	06 Apr 2021 17:25:35

US3892032

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:18:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:55:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered '0'	Andryelle Toledo (b) (4)	06 Apr 2021 17:25:35

US3892032

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:18:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:55:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered '0'	Andryelle Toledo (b) (4)	06 Apr 2021 17:25:35

US3892032

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:18:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:55:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered '0'	Andryelle Toledo (b) (4)	06 Apr 2021 17:25:35

US3892032

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:18:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:55:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered empty.	Andryelle Toledo (b) (4)	06 Apr 2021 17:25:35

US3892032

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:18:29

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:55:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered empty.	Andryelle Toledo (b) (4)	06 Apr 2021 17:25:35

US3892032

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:18:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:55:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered empty.	Andryelle Toledo (b) (4)	06 Apr 2021 17:25:35

US3892032

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:18:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:55:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered empty.	Andryelle Toledo (b) (4)	06 Apr 2021 17:25:35

US3892032

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:18:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:55:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered '0'	Andryelle Toledo (b) (4)	06 Apr 2021 17:25:35

US3892032

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:18:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:55:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered '0'	Andryelle Toledo (b) (4)	06 Apr 2021 17:25:35

US3892032

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:18:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:55:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered '0'	Andryelle Toledo (b) (4)	06 Apr 2021 17:25:35

US3892032

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:18:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:55:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered 'Not Related (NOT RELATED)'	Andryelle Toledo (b) (4)	06 Apr 2021 17:25:35

US3892032

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:18:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:55:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered 'Not Related (NOT RELATED)'	Andryelle Toledo (b) (4)	06 Apr 2021 17:25:35

US3892032

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:18:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:55:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Andryelle Toledo (b) (4)	06 Apr 2021 17:25:35

US3892032

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:18:29

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:55:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered 'I'	Andryelle Toledo (b) (4)	06 Apr 2021 17:25:35

US3892032

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: AE MENISCUS TEAR LEFT KNEE is recorded with start date-22MAR2021 , however concomitant medication for the same is not checked or recorded, please confirm or explain. Thank you.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 08:33:21
User signature succeeded.	(b) (4), (b) (6)	12 Apr 2021 17:55:02
Query 'Per CDM: AE MENISCUS TEAR LEFT KNEE is recorded with start date-22MAR2021 , however concomitant medication for the same is not checked or recorded, please confirm or explain. Thank you.' answered with 'No medication used. ' (Site from DM).	Michael Adams (b) (4) (b) (4)	12 Apr 2021 16:25:47
User opened query 'Per CDM: AE MENISCUS TEAR LEFT KNEE is recorded with start date-22MAR2021 , however concomitant medication for the same is not checked or recorded, please confirm or explain. Thank you.' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	12 Apr 2021 14:39:36
User entered '0'	(b) (4), (b) (6)	10 Apr 2021 07:34:02
	Andryelle Toledo (b) (4) (b) (4)	06 Apr 2021 17:25:35

US3892032

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:55:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered '0'	Andryelle Toledo (b) (4)	06 Apr 2021 17:25:35

US3892032

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:18:29

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:55:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Andryelle Toledo (b) (4)	06 Apr 2021 17:25:35

US3892032

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:18:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:55:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered empty.	Andryelle Toledo (b) (4)	06 Apr 2021 17:25:35

US3892032

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:18:29

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:55:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User entered empty.	Andryelle Toledo (b) (4)	06 Apr 2021 17:25:35

US3892032

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:18:29

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Apr 2021 17:25:35

US3892032

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 10 Jun 2021 10:18:29

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	06 Apr 2021 17:25:35

US3892032

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:18:29

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	28 Apr 2021 17:48:36
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	26 Apr 2021 17:15:11
User entered		
'USA-US209-2021-mRNA-1273-P301000005'	System	26 Apr 2021 17:15:03
User entered 'New'	(b) (4), (b) (6)	26 Apr 2021 17:15:03

US3892032

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:18:29

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	28 Apr 2021 17:48:36
	(b) (4)	
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Fractures and dislocations NEC, PT: Stress fracture, LLT: Stress fracture - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 21:28:09
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 21:28:09
	(b) (4)	
Data point term sent to Coder	System	23 Apr 2021 21:26:48
User entered 'stress fracture left foot'	Rachel Law (b) (4)	23 Apr 2021 21:26:45
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:18:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	28 Apr 2021 17:48:36
	(b) (4)	
User entered 'Yes (Y)'	Rachel Law (b) (4)	23 Apr 2021 21:26:45
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:18:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	28 Apr 2021 17:48:36
	(b) (4)	
User entered 'No (N)'	Rachel Law (b) (4)	23 Apr 2021 21:26:45
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:18:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	28 Apr 2021 17:48:36
	(b) (4)	
User entered 'No (N)'	Rachel Law (b) (4)	23 Apr 2021 21:26:45
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:18:29

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	28 Apr 2021 17:48:36
	(b) (4)	
User entered '22 Mar 2021'	Rachel Law (b) (4)	23 Apr 2021 21:26:45
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:18:29

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	28 Apr 2021 17:48:36
	(b) (4)	
User entered empty.	Rachel Law (b) (4)	23 Apr 2021 21:26:45
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:18:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 21:26:45

US3892032

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	28 Apr 2021 17:48:36
	(b) (4)	
User entered 'Yes (Y)'	Rachel Law (b) (4)	23 Apr 2021 21:26:45
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:18:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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). User signature succeeded.	(b) (4), (b) (6) (b) (4)	03 May 2021 22:07:04
User entered empty.	Michael Adams (b) (4) (b) (4) Rachel Law (b) (4) (b) (4)	28 Apr 2021 17:48:36 23 Apr 2021 21:26:45

US3892032

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:18:29

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	28 Apr 2021 17:48:36
	(b) (4)	
User entered empty.	Rachel Law (b) (4)	23 Apr 2021 21:26:45
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:18:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 21:26:45

US3892032

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:18:29

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	28 Apr 2021 17:48:36
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Rachel Law (b) (4)	23 Apr 2021 21:26:45
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:18:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	28 Apr 2021 17:48:36
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4) System	23 Apr 2021 21:27:15
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	23 Apr 2021 21:26:45
User entered 'Yes (Y)'	Rachel Law (b) (4) (b) (4)	23 Apr 2021 21:26:45

US3892032

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:18:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	28 Apr 2021 17:48:36
	(b) (4)	
User entered '0'	Rachel Law (b) (4)	23 Apr 2021 21:26:45
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:18:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	28 Apr 2021 17:48:36
	(b) (4)	
User entered '0'	Rachel Law (b) (4)	23 Apr 2021 21:26:45
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:18:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'PER CDM: RE-QUERY: Per response 'planned discharge is 23Apr21, will update when site can confirm'. Please update the Hospital Discharge date as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 05:04:34
User signature succeeded.	Michael Adams (b) (4)	28 Apr 2021 17:48:36
Query 'PER CDM: RE-QUERY: Per response 'planned discharge is 23Apr21, will update when site can confirm'. Please update the Hospital Discharge date as appropriate. Thank you. ' answered with 'confirm discharge date of 26Apr21' (Site from DM).	Rachel Law (b) (4)	27 Apr 2021 19:10:01
User opened query 'PER CDM: RE-QUERY: Per response 'planned discharge is 23Apr21, will update when site can confirm'. Please update the Hospital Discharge date as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 13:45:39
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	26 Apr 2021 13:44:38
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'planned discharge is 23Apr21, will update when site can confirm' (Site from System).	Rachel Law (b) (4)	23 Apr 2021 21:27:47
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	23 Apr 2021 21:27:15
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	23 Apr 2021 21:27:15
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	23 Apr 2021 21:27:15

PRODUCTION RELEASE (v12.003
EAB) (1725)

3876 of 4365

US3892032

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:18:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Rachel Law (b) (4)	23 Apr 2021 21:27:15
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4) System	23 Apr 2021 21:26:45
User entered '0'	Rachel Law (b) (4)	23 Apr 2021 21:26:45
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:18:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	28 Apr 2021 17:48:36
	(b) (4)	
User entered '22 Apr 2021'	Rachel Law (b) (4)	23 Apr 2021 21:26:45
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:18:29

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	28 Apr 2021 17:48:36
	(b) (4)	
User entered '26 Apr 2021' reason for change: New Information	Rachel Law (b) (4)	27 Apr 2021 19:09:38
	(b) (4)	
User entered empty.	Rachel Law (b) (4)	23 Apr 2021 21:26:45
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:18:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	28 Apr 2021 17:48:36
	(b) (4)	
User entered 'No (N)'	Rachel Law (b) (4)	23 Apr 2021 21:26:45
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:18:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	28 Apr 2021 17:48:36
	(b) (4)	
User entered empty.	Rachel Law (b) (4)	23 Apr 2021 21:26:45
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:18:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	28 Apr 2021 17:48:36
	(b) (4)	
User entered '0'	Rachel Law (b) (4)	23 Apr 2021 21:26:45
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:18:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	28 Apr 2021 17:48:36
	(b) (4)	
User entered '0'	Rachel Law (b) (4)	23 Apr 2021 21:26:45
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:18:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	28 Apr 2021 17:48:36
	(b) (4)	
User entered '0'	Rachel Law (b) (4)	23 Apr 2021 21:26:45
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:18:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	28 Apr 2021 17:48:36
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Rachel Law (b) (4)	23 Apr 2021 21:26:45
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:18:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	28 Apr 2021 17:48:36
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Rachel Law (b) (4)	23 Apr 2021 21:26:45
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:18:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	28 Apr 2021 17:48:36
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Rachel Law (b) (4)	23 Apr 2021 21:26:45
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:18:29

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	28 Apr 2021 17:48:36
	(b) (4)	
User entered '0'	Rachel Law (b) (4)	23 Apr 2021 21:26:45
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	28 Apr 2021 17:48:36
	(b) (4)	
User entered '0'	Rachel Law (b) (4)	23 Apr 2021 21:26:45
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:18:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	28 Apr 2021 17:48:36
	(b) (4)	
User entered 'I'	Rachel Law (b) (4)	23 Apr 2021 21:26:45
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:18:29

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 22:07:15
User signature succeeded.	Michael Adams (b) (4)	28 Apr 2021 17:48:36
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Apr 2021 21:27:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Apr 2021 21:27:15
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Rachel Law (b) (4)	23 Apr 2021 21:27:15
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 21:26:45
User entered empty.	Rachel Law (b) (4)	23 Apr 2021 21:26:45

US3892032

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:18:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	28 Apr 2021 17:48:36
	(b) (4)	
User entered empty.	Rachel Law (b) (4)	23 Apr 2021 21:26:45
	(b) (4)	

US3892032

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:18:29

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 22:08:29
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 22:07:45
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. 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)	03 May 2021 22:07:37
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)	03 May 2021 22:07:26
User signature succeeded.	Michael Adams (b) (4)	28 Apr 2021 17:48:36
User entered 'Subject was hospitalized for an elective surgical procedure to repair fix damage left foot. Although the surgery was elective and not emergency surgery, it will be considered an SAE per section 8.3.3'	Rachel Law (b) (4)	23 Apr 2021 21:26:45

US3892032

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:18:29

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Apr 2021 21:26:45

US3892032

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:18:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Apr 2021 21:26:45

US3892032

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 10:18:29

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Apr 2021 21:26:45

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:18:29

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:54:30
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 06:35:34
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' answered with 'This query is wrong. The filler was reported, it is related with the conc. med # 22. ' (Site from DM).	Andryelle Toledo (b) (4)	23 Mar 2021 14:56:05
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 10:27:49
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2-7, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 11:31:19

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:18:29

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Query 'Per DM CLR: Per Diary Dose 2 Day 2-7, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'Subject used Conc. Medication # 11 (Theraflu) 29 Sep. 2020 to 12 Oct. 2020. Medication associated with Solicited AE and Unsolicited AE.' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	23 Feb 2021 20:45:04
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2-7, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Feb 2021 10:43:06
	(b) (4), (b) (6) (b) (4)	16 Sep 2020 16:09:31
User entered 'Yes (Y)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:56:21

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:18:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:59:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:59:39
Data point term sent to Coder	System	31 Aug 2020 21:57:59
User entered 'trazadone'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:57:07

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:18:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'No (N)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:57:07

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:18:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'Insomnia'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:57:07

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:18:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered '100'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:57:07

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:18:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'mg (mg)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:57:07

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:18:29

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:57:07

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:18:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'once daily (QD)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:57:07

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:18:29

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:57:07

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:18:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'Oral (ORAL)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:57:07

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:18:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:57:07

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'un UNK 2011'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:57:07

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered '0'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:57:07

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'Yes (Y)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:57:07

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:18:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:57:07

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:18:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'No (N)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:57:07

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:18:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 21:57:07

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 21:57:07

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 21:57:07

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:18:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTI-PARKINSON DRUGS, ATC: DOPAMINERGIC AGENTS, ATC: DOPAMINE AGONISTS, PRODUCT: PRAMIPEXOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 08:24:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 08:24:44
Data point term sent to Coder	System	31 Aug 2020 21:58:00
User entered 'Pramipexole'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:57:53

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:18:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'No (N)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:57:53

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:18:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'restless leg syndrom'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:57:53

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:18:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 21:25:47
DataPoint Un-verified.		
	Andryelle Toledo (b) (4)	01 Oct 2020 13:37:03
	(b) (4)	
User entered '1.0' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	01 Oct 2020 13:37:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered '.25'	chase Carnahan (b) (4)	31 Aug 2020 21:57:53
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:18:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'mg (mg)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:57:53

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:18:29

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:57:53

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:18:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'once daily (QD)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:57:53

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:18:29

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:57:53

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:18:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'Oral (ORAL)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:57:53

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:18:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:57:53

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'un UNK 2011'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:57:53

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered '0'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:57:53

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'Yes (Y)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:57:53

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:18:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:57:53

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:18:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'No (N)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:57:53

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:18:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 21:57:53

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 21:57:53

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 21:57:53

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:18:29

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: PREGABALIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Sep 2020 10:20:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Sep 2020 10:20:40
Data point term sent to Coder	System	18 Sep 2020 16:52:03
Coding entries removed.	Andryelle Toledo (b) (4)	18 Sep 2020 16:51:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: PREGABALIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:59:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:59:40
Data point term sent to Coder	System	31 Aug 2020 21:59:01
User entered 'pregabalin'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:58:30

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:18:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'No (N)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:58:30

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:18:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Sep 2020 21:46:50
User closed query 'Per DM CLR: Please update the indication and clarify the type and location of the NEUROPATHY (i.e. sensory or motor; Bilateral, left, Right; Arm or legs). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 05:42:12
Query 'Per DM CLR: Please update the indication and clarify the type and location of the NEUROPATHY (i.e. sensory or motor; Bilateral, left, Right; Arm or legs). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'update' (Site from DM).	Andryelle Toledo (b) (4)	18 Sep 2020 16:51:40
	(b) (4)	
DataPoint Un-verified.	Andryelle Toledo (b) (4)	18 Sep 2020 16:51:32
	(b) (4)	
User entered 'sensory PERIPHERAL NEUROPATHY bilateral legs' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	18 Sep 2020 16:51:32
	(b) (4)	
User opened query 'Per DM CLR: Please update the indication and clarify the type and location of the NEUROPATHY (i.e. sensory or motor; Bilateral, left, Right; Arm or legs). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 11:23:34
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'peripheral neuropathy'	chase Carnahan (b) (4)	31 Aug 2020 21:58:30
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:18:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:25:47
DataPoint Un-verified.	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:37:28
User entered '200' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:37:28
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered '50'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:58:30

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:18:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'mg (mg)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:58:30

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:18:29

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:58:30

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:18:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'once daily (QD)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:58:30

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:18:29

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:58:30

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:18:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'Oral (ORAL)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:58:30

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:18:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:58:30

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'un UNK 2015'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:58:30

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered '0'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:58:30

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'Yes (Y)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:58:30

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:18:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:58:30

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:18:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'No (N)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:58:30

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:18:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 21:58:30

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 21:58:30

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 21:58:30

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:18:29

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 16:09:44
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 22:00:41
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 22:00:41
	(b) (4)	
Data point term sent to Coder	System	31 Aug 2020 22:00:03
User entered 'cyclobenzaprine'	chase Carnahan (b) (4)	31 Aug 2020 21:59:16
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:18:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'No (N)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:59:16

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:18:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'lower back pain'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:59:16

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:18:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 21:25:47
DataPoint Un-verified.		
	Andryelle Toledo (b) (4)	01 Oct 2020 13:37:49
	(b) (4)	
User entered '5' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	01 Oct 2020 13:37:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered '10'	chase Carnahan (b) (4)	31 Aug 2020 21:59:16
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:18:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'mg (mg)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:59:16

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:18:29

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:59:16

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:18:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'once daily (QD)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:59:16

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:18:29

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:59:16

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:18:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'Oral (ORAL)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:59:16

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:18:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:59:16

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'un UNK 2015'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:59:16

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered '0'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:59:16

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'Yes (Y)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:59:16

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:18:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:59:16

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:18:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'No (N)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:59:16

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:18:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 21:59:16

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 21:59:16

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 21:59:16

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:18:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ENDOCRINE THERAPY, ATC: HORMONES AND RELATED AGENTS, ATC: ESTROGENS, PRODUCT: ESTRADIOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	24 Sep 2020 21:54:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 21:54:33
Data point term sent to Coder Coding entries removed.	System Andryelle Toledo (b) (4)	22 Sep 2020 16:26:44 22 Sep 2020 16:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 22:00:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 22:00:41
Data point term sent to Coder User entered 'estrodial'	System chase Carnahan (b) (4) (b) (4)	31 Aug 2020 22:00:04 31 Aug 2020 21:59:48

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:18:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'No (N)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:59:48

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:18:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:46:50
User closed query 'PER CDM: Re-Query: Please update the indication to reflect the any one of underlying medical conditions that this medication is being used to prevent/treat. Please reconcile and Update eCRF as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 05:38:44
Query 'PER CDM: Re-Query: Please update the indication to reflect the any one of underlying medical conditions that this medication is being used to prevent/treat. Please reconcile and Update eCRF as appropriate. Thank you.' answered with 'update' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	22 Sep 2020 16:26:19
DataPoint Un-verified.	Andryelle Toledo (b) (4) (b) (4)	22 Sep 2020 16:25:46
User entered 'Post menopausal (HORMONE REPLACEMENT)' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	22 Sep 2020 16:25:46
User opened query 'PER CDM: Re-Query: Please update the indication to reflect the any one of underlying medical conditions that this medication is being used to prevent/treat. Please reconcile and Update eCRF as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 08:23:03
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile and Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 08:23:03
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile and Update eCRF as appropriate. ' answered with 'update' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	18 Sep 2020 16:57:43
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile and Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 11:24:28

PRODUCTION RELEASE (v12.003
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3973 of 4365

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:18:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'hormone replacement'	chase Carnahan (b) (4)	31 Aug 2020 21:59:48
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:18:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Sep 2020 21:46:50
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 05:39:07
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'update' (Site from DM).	Andryelle Toledo (b) (4)	18 Sep 2020 16:57:47
DataPoint Un-verified.	(b) (4)	
	Andryelle Toledo (b) (4)	18 Sep 2020 16:57:33
User entered '0.5' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	18 Sep 2020 16:57:33
	(b) (4)	
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 11:24:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered '5'	chase Carnahan (b) (4)	31 Aug 2020 21:59:48
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:18:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'mg (mg)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:59:48

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:18:29

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:59:48

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:18:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'once daily (QD)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:59:48

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:18:29

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:59:48

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:18:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'Oral (ORAL)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:59:48

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:18:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:59:48

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'un UNK 2003'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:59:48

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered '0'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:59:48

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'Yes (Y)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:59:48

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:18:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:59:48

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:18:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 21:59:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 21:59:56
User entered 'No (N)' reason for change: Data Entry Error	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:59:56
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 21:59:48
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 21:59:48

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:18:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 21:59:48

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 21:59:48

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 21:59:48

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:18:29

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:34:07
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Per DM CLR: Kindly review if this Con Med is a Combination Medication of Hydrocodone-Acetaminophen 7.5mg/325mg or 7.5mg/500mg. If yes, Update the Medication Name and Dose Unit fields accordingly. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 09:34:37
Query 'Per DM CLR: Kindly review if this Con Med is a Combination Medication of Hydrocodone-Acetaminophen 7.5mg/325mg or 7.5mg/500mg. If yes, Update the Medication Name and Dose Unit fields accordingly. Otherwise, provide clarification.' answered with 'update' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	11 Feb 2021 20:39:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN;HYDROCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 19:39:56
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 Feb 2021 19:39:56
Data point term sent to Coder	System	11 Feb 2021 19:38:54
DataPoint Un-verified.	Andryelle Toledo (b) (4) (b) (4)	11 Feb 2021 19:38:21
Coding entries removed.	Andryelle Toledo (b) (4) (b) (4)	11 Feb 2021 19:38:21
User entered 'Hydrocodone-Acetaminophen' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	11 Feb 2021 19:38:21
User opened query 'Per DM CLR: Kindly review if this Con Med is a Combination Medication of Hydrocodone-Acetaminophen 7.5mg/325mg or 7.5mg/500mg. If yes, Update the Medication Name and Dose Unit fields accordingly. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 06:33:09
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:09:44

PRODUCTION RELEASE (v12.003
EAB) (1725)

3990 of 4365

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:18:29

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 22:01:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 22:01:43
Data point term sent to Coder	System	31 Aug 2020 22:01:05
User entered 'hydrocodone'	chase Carnahan (b) (4)	31 Aug 2020 22:00:56

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:18:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'No (N)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 22:00:56

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:18:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'lower back pain'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 22:00:56

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:18:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:40:07
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Un-verified.	Andryelle Toledo (b) (4)	11 Feb 2021 19:38:21
User entered '7.5/325' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	11 Feb 2021 19:38:21
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered '7.5'	chase Carnahan (b) (4)	31 Aug 2020 22:00:56

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:18:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'mg (mg)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 22:00:56

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:18:29

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 22:00:56

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:18:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'as needed (PRN)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 22:00:56

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:18:29

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 22:00:56

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:18:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'Oral (ORAL)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 22:00:56

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:18:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 22:00:56

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User closed query 'Per DM CLR: Thank you for the response but it was noted that the start date of this medication is still prior to the start date of the corresponding MH condition. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 05:56:19
Query 'Per DM CLR: Thank you for the response but it was noted that the start date of this medication is still prior to the start date of the corresponding MH condition. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' answered with 'Back pain and medication started in 2015. Entry error corrected.' (Site from DM).	Leslie Iverson (b) (4)	18 Nov 2020 17:06:34
	(b) (4)	
DataPoint Un-verified.	Leslie Iverson (b) (4)	18 Nov 2020 17:06:08
	(b) (4)	
User entered 'UN UNK 2015' reason for change:	Leslie Iverson (b) (4)	18 Nov 2020 17:06:08
Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Thank you for the response but it was noted that the start date of this medication is still prior to the start date of the corresponding MH condition. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 14:55:44
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:25:47
User closed query 'Per source the year is noted as 2014, kindly confirm which data point is accurate and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	08 Oct 2020 20:18:57
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 06:46:50
Query 'Per source the year is noted as 2014, kindly confirm which data point is accurate and update accordingly.' answered with 'update' (Site from CRA).	Andryelle Toledo (b) (4)	01 Oct 2020 13:38:21
	(b) (4)	
DataPoint Un-verified.	Andryelle Toledo (b) (4)	01 Oct 2020 13:38:14
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN UNK 2014' reason for change:	Andryelle Toledo (b) (4)	01 Oct 2020 13:38:14
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:46:50
	(b) (4), (b) (6)	30 Sep 2020 21:45:54
User opened query 'Per source the year is noted as 2014, kindly confirm which data point is accurate and update accordingly.' (Site from CRA).		
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'corrected' (Site from DM).	Stefanie Vasconez (b) (4)	29 Sep 2020 17:57:50
DataPoint Un-verified.	(b) (4)	
	Stefanie Vasconez (b) (4)	29 Sep 2020 17:57:43
	(b) (4)	
User entered 'UN UNK 2015' reason for change:	Stefanie Vasconez (b) (4)	29 Sep 2020 17:57:43
Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Sep 2020 15:16:27
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:09:44
	(b) (4)	
User entered 'un UNK 2014'	chase Carnahan (b) (4)	31 Aug 2020 22:00:56
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered '0'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 22:00:56

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'Yes (Y)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 22:00:56

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:18:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 22:00:56

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:18:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'No (N)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 22:00:56

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:18:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 22:00:56

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 22:00:56

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 22:00:56

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:18:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Per source subject is noted as using omeprazole, restasis, and amoxicillin. Kindly update EDC.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:19:08
Query 'Per source subject is noted as using omeprazole, restasis, and amoxicillin. Kindly update EDC.' answered with 'update' (Site from CRA).	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:38:40
User opened query 'Per source subject is noted as using omeprazole, restasis, and amoxicillin. Kindly update EDC.' (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 21:48:44
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:09:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: DIAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 22:02:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 22:02:45
Data point term sent to Coder	System	31 Aug 2020 22:02:09
User entered 'diazepam'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 22:01:31

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:18:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'No (N)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 22:01:31

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:18:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'anxiety'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 22:01:31

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:18:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered '5'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 22:01:31

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:18:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'mg (mg)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 22:01:31

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:18:29

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 22:01:31

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:18:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'as needed (PRN)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 22:01:31

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:18:29

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 22:01:31

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:18:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'Oral (ORAL)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 22:01:31

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:18:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 22:01:31

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'un UNK 2013'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 22:01:31

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered '0'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 22:01:31

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'Yes (Y)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 22:01:31

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:18:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered empty.	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 22:01:31

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:18:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:09:44
User entered 'No (N)'	chase Carnahan (b) (4) (b) (4)	31 Aug 2020 22:01:31

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:18:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 22:01:31

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 22:01:31

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 22:01:31

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:18:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:54
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Dec 2020 22:38:52
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Dec 2020 22:38:52
	(b) (4)	
Data point term sent to Coder	System	21 Dec 2020 22:37:42
Coding entries removed.	Leslie Iverson (b) (4)	21 Dec 2020 22:36:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:25:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 13:41:55
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 13:41:55
	(b) (4)	
Data point term sent to Coder	System	01 Oct 2020 13:40:44
User entered 'omeprazole'	Andryelle Toledo (b) (4)	01 Oct 2020 13:39:53
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:18:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:54
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered 'No (N)'	Andryelle Toledo (b) (4)	01 Oct 2020 13:39:53
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:18:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:54
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 19:06:34
DataPoint Un-verified.	Leslie Iverson (b) (4)	21 Dec 2020 22:36:59
	(b) (4)	
User entered 'Gastroesophageal reflux disease'	Leslie Iverson (b) (4)	21 Dec 2020 22:36:59
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered 'Acid Reflux'	Andryelle Toledo (b) (4)	01 Oct 2020 13:39:53
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:18:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:54
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered '40'	Andryelle Toledo (b) (4)	01 Oct 2020 13:39:53
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:18:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:54
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered 'mg (mg)'	Andryelle Toledo (b) (4)	01 Oct 2020 13:39:53
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:18:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:54
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered empty.	Andryelle Toledo (b) (4)	01 Oct 2020 13:39:53
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:18:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:54
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered 'once daily (QD)'	Andryelle Toledo (b) (4)	01 Oct 2020 13:39:53
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:18:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:54
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered empty.	Andryelle Toledo (b) (4)	01 Oct 2020 13:39:53
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:18:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:54
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered 'Oral (ORAL)'	Andryelle Toledo (b) (4)	01 Oct 2020 13:39:53
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:18:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:54
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered empty.	Andryelle Toledo (b) (4)	01 Oct 2020 13:39:53
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:54
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered 'un UNK 2019'	Andryelle Toledo (b) (4)	01 Oct 2020 13:39:53
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:54
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered '0'	Andryelle Toledo (b) (4)	01 Oct 2020 13:39:53
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:54
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
DataPoint Un-verified.	Andryelle Toledo (b) (4)	18 Nov 2020 01:04:54
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	18 Nov 2020 01:04:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	01 Oct 2020 13:39:53
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:18:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:54
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
DataPoint Un-verified.	Andryelle Toledo (b) (4)	18 Nov 2020 01:04:54
	(b) (4)	
User entered '12 Nov 2020' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	18 Nov 2020 01:04:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered empty.	Andryelle Toledo (b) (4)	01 Oct 2020 13:39:53
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:18:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:54
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered 'No (N)'	Andryelle Toledo (b) (4)	01 Oct 2020 13:39:53
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:18:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:54
User entered '1'	System	01 Oct 2020 13:39:53

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:54
User entered '1'	System	01 Oct 2020 13:39:53

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:54
User entered '804 (804)'	System	01 Oct 2020 13:39:53

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:18:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 21:25:47
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, PRODUCT: CICLOSPORIN, PRODUCTSYNONYM: RESTASIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 09:10:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 09:10:43
Data point term sent to Coder	System	01 Oct 2020 13:41:45
User entered 'Restasis 0.05%'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:41:37

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:18:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:41:37

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:18:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered 'Bilateral Dry Eyes'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:41:37

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:18:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered 'I'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:41:37

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:18:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered 'Other (OTHER)'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:41:37

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:18:29

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered 'Drop in each eye'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:41:37

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:18:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered 'twice daily (BID)'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:41:37

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:18:29

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:41:37

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:18:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered 'Other (OTHER)'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:41:37

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:18:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered 'ophthalmic'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:41:37

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered 'un UNK 2018'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:41:37

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:41:37

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:41:37

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:18:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:41:37

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:18:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:41:37

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:18:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	01 Oct 2020 13:41:37

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 13:41:37

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 13:41:37

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:18:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:25:47
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 13:44:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 13:44:51
Data point term sent to Coder	System	01 Oct 2020 13:43:47
User entered 'Amoxicillin'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:43:09

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:18:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	01 Oct 2020 13:43:09
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:18:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Per DM CLR: Dental Prophylaxis was noted. Please verify if there was a dental procedure performed during the date of this medication. If yes please note, there is no corresponding Concomitant Procedures record that match this indication. Please update to record the corresponding procedure as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 05:56:53
Query 'Per DM CLR: Dental Prophylaxis was noted. Please verify if there was a dental procedure performed during the date of this medication. If yes please note, there is no corresponding Concomitant Procedures record that match this indication. Please update to record the corresponding procedure as appropriate. Otherwise, clarify. ' answered with 'Routine Dental Cleaning added to procedures for clarification.' (Site from DM).	Leslie Iverson (b) (4) (b) (4)	18 Nov 2020 17:27:08
User opened query 'Per DM CLR: Dental Prophylaxis was noted. Please verify if there was a dental procedure performed during the date of this medication. If yes please note, there is no corresponding Concomitant Procedures record that match this indication. Please update to record the corresponding procedure as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 14:51:22
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered 'dental prophylaxis'	Andryelle Toledo (b) (4) (b) (4)	01 Oct 2020 13:43:09

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:18:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered '1000'	Andryelle Toledo (b) (4)	01 Oct 2020 13:43:09
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:18:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered 'mg (mg)'	Andryelle Toledo (b) (4)	01 Oct 2020 13:43:09
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:18:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered empty.	Andryelle Toledo (b) (4)	01 Oct 2020 13:43:09
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:18:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered 'once (ONCE)'	Andryelle Toledo (b) (4)	01 Oct 2020 13:43:09
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:18:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered empty.	Andryelle Toledo (b) (4)	01 Oct 2020 13:43:09
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:18:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered 'Oral (ORAL)'	Andryelle Toledo (b) (4)	01 Oct 2020 13:43:09
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:18:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered empty.	Andryelle Toledo (b) (4)	01 Oct 2020 13:43:09
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:18:29

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered '24 Sep 2020'	Andryelle Toledo (b) (4)	01 Oct 2020 13:43:09
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered '0'	Andryelle Toledo (b) (4)	01 Oct 2020 13:43:09
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered 'No (N)'	Andryelle Toledo (b) (4)	01 Oct 2020 13:43:09
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:18:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered '24 Sep 2020'	Andryelle Toledo (b) (4)	01 Oct 2020 13:43:09
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:18:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 21:25:47
User entered 'No (N)'	Andryelle Toledo (b) (4)	01 Oct 2020 13:43:09
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:18:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:58
User entered empty.	System	01 Oct 2020 13:43:09

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:58
User entered empty.	System	01 Oct 2020 13:43:09

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:58
User entered empty.	System	01 Oct 2020 13:43:09

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:18:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL;PHENYLE PHRINE HYDROCHLORIDE, PRODUCTSYNONYM: THERAFLU NIGHTTIME MULTI SYMPTOM SEVERE COLD - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 10:19:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 10:19:50
Data point term sent to Coder	System	05 Mar 2021 16:51:32
Data point term sent to Coder	System	05 Mar 2021 16:47:24
Coding entries removed.	Andryelle Toledo (b) (4) (b) (4)	05 Mar 2021 16:46:27
User signature succeeded.	Michael Adams (b) (4) (b) (4)	23 Feb 2021 18:10:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL;PHENYLE PHRINE HYDROCHLORIDE, PRODUCTSYNONYM: THERAFLU NIGHTTIME MULTI SYMPTOM SEVERE COLD - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Jan 2021 18:32:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Jan 2021 18:32:43
Data point term sent to Coder	System	31 Dec 2020 00:53:51
Coding entries removed.	Andryelle Toledo (b) (4) (b) (4)	31 Dec 2020 00:53:02

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:18:29

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL;PHENYLE PHRINE HYDROCHLORIDE, PRODUCTSYNONYM: THERAFLU COLD & COUGH NIGHTTIME - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 12:06:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 12:06:06
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	23 Nov 2020 20:35:04
Data point term sent to Coder	System	19 Nov 2020 23:08:14
Coding entries removed.	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 23:07:56
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL;PHENYLE PHRINE HYDROCHLORIDE, PRODUCTSYNONYM: THERAFLU COLD & COUGH NIGHTTIME - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 15:09:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 15:09:47
Data point term sent to Coder	System	11 Nov 2020 21:28:53
User closed query 'For coding purposes, references indicate different formulations for THERAFLU. Please provide generic ingredients, complete, accurate trade name and update the term with your response ' (Site from System).	System	11 Nov 2020 21:28:16
Query 'For coding purposes, references indicate different formulations for THERAFLU. Please provide generic ingredients, complete, accurate trade name and update the term with your response ' answered with 'Updated ingredients' (Site from System).	Leslie Iverson (b) (4) (b) (4)	11 Nov 2020 21:28:16

PRODUCTION RELEASE (v12.003
EAB) (1725)

4083 of 4365

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:18:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Leslie Iverson (b) (4)	11 Nov 2020 21:27:56
User entered 'THERAFLU MULTISYMPTOM: Acetaminophen, Dyphenhydramine HCL, Phenylephrine HCL' reason for change: Data Entry Error	Leslie Iverson (b) (4)	11 Nov 2020 21:27:56
User opened query 'For coding purposes, references indicate different formulations for THERAFLU. Please provide generic ingredients, complete, accurate trade name and update the term with your response ' (Site from System).	Coder Import (b) (4)	08 Nov 2020 22:15:37
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:54:51
Data point term sent to Coder	System	21 Oct 2020 14:11:27
User entered 'Theraflu'	Andryelle Toledo (b) (4)	21 Oct 2020 14:11:25
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:18:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:54:51
User entered 'No (N)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:11:25
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:18:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:17
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:25:51
	(b) (4)	
User entered 'VIRAL SYNDROME and HEADACHE' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	05 Mar 2021 16:51:27
DataPoint Un-verified.	(b) (4)	
	Andryelle Toledo (b) (4)	05 Mar 2021 16:46:27
	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	05 Mar 2021 16:46:27
	(b) (4)	
User entered 'VIRAL SYNDROME, Headache, Myalgia and Arthralgia' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	05 Mar 2021 16:46:27
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 19:06:55
	(b) (4)	
DataPoint Un-verified.	Andryelle Toledo (b) (4)	31 Dec 2020 00:53:02
	(b) (4)	
User entered 'Viral Syndrome' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	31 Dec 2020 00:53:02
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
	(b) (4)	
User closed query 'Per CDM: Please note that on the AE eCRF, for this corresponding Con Med indication, it is recorded with the term "Upper respiratory infection" with the same start and end dates. Please review and reconcile accordingly, if necessary or provide clarification. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 13:47:19
	(b) (4)	
Query 'Per CDM: Please note that on the AE eCRF, for this corresponding Con Med indication, it is recorded with the term "Upper respiratory infection" with the same start and end dates. Please review and reconcile accordingly, if necessary or provide clarification. Thank you.' answered with 'update' (Site from DM).	Andryelle Toledo (b) (4)	19 Nov 2020 23:08:06
	(b) (4)	
DataPoint Un-verified.	Andryelle Toledo (b) (4)	19 Nov 2020 23:07:56
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:18:29

[Indication](#)

Audit	User	Time (GMT)
User entered 'UPPER RESPIRATORY TRACT INFECTION' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	19 Nov 2020 23:07:56
User opened query 'Per CDM: Please note that on the AE eCRF, for this corresponding Con Med indication, it is recorded with the term "Upper respiratory infection" with the same start and end dates. Please review and reconcile accordingly, if necessary or provide clarification. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 07:16:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:54:51
User entered 'Acute Respiratory Infection'	Andryelle Toledo (b) (4)	21 Oct 2020 14:11:25
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:18:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:54:51
User entered 'I'	Andryelle Toledo (b) (4)	21 Oct 2020 14:11:25
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:18:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:54:51
User entered 'Other (OTHER)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:11:25
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:18:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:54:51
User entered 'Packet'	Andryelle Toledo (b) (4)	21 Oct 2020 14:11:25
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:18:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:54:51
User entered 'once daily (QD)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:11:25
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:18:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:54:51
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 14:11:25
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:18:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:54:51
User entered 'Oral (ORAL)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:11:25
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:18:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:54:51
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 14:11:25
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:54:51
User entered '29 Sep 2020' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	21 Oct 2020 21:51:24
	(b) (4)	
User entered '30 Sep 2020'	Andryelle Toledo (b) (4)	21 Oct 2020 14:11:25
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:54:51
User entered '0'	Andryelle Toledo (b) (4)	21 Oct 2020 14:11:25
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:17
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
	(b) (4)	
User closed query 'Kindly confirm if this is 'ongoing' or if this has ended and update EDC/Source accordingly.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 22:03:01
Query 'Kindly confirm if this is 'ongoing' or if this has ended and update EDC/Source accordingly.' answered with 'Stopped once AE resolved' (Site from CRA).	Leslie Iverson (b) (4)	11 Nov 2020 21:28:35
	(b) (4)	
DataPoint Un-verified.	Leslie Iverson (b) (4)	11 Nov 2020 21:27:56
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Leslie Iverson (b) (4)	11 Nov 2020 21:27:56
	(b) (4)	
User opened query 'Kindly confirm if this is 'ongoing' or if this has ended and update EDC/Source accordingly.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 19:09:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:54:51
	(b) (4)	
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:11:25
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:18:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
DataPoint Un-verified.	Leslie Iverson (b) (4)	11 Nov 2020 21:27:56
	(b) (4)	
User entered '12 Oct 2020' reason for change: Data Entry Error	Leslie Iverson (b) (4)	11 Nov 2020 21:27:56
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:54:51
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 14:11:25
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:18:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
DataPoint Un-verified.	Leslie Iverson (b) (4)	18 Nov 2020 18:27:24
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Leslie Iverson (b) (4)	18 Nov 2020 18:27:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:54:51
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:11:25
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:18:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:17
User entered '1'	System	21 Oct 2020 14:11:25

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:17
User entered '1'	System	21 Oct 2020 14:11:25

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:17
User entered '804 (804)'	System	21 Oct 2020 14:11:25

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:18:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:19
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Dec 2020 00:54:23
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	31 Dec 2020 00:54:23
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	31 Dec 2020 00:53:51
Coding entries removed.	Andryelle Toledo (b) (4)	31 Dec 2020 00:53:17
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:54:51
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 14:13:32
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	21 Oct 2020 14:13:32
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	21 Oct 2020 14:12:32
User entered 'Ibuprofen'	Andryelle Toledo (b) (4)	21 Oct 2020 14:12:05
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:18:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:19
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:54:51
User entered 'No (N)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:12:05
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:18:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:19
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 19:07:05
DataPoint Un-verified.	Andryelle Toledo (b) (4)	31 Dec 2020 00:53:17
	(b) (4)	
User entered 'Viral Syndrome' reason for change:	Andryelle Toledo (b) (4)	31 Dec 2020 00:53:17
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:54:51
User entered 'Headache'	Andryelle Toledo (b) (4)	21 Oct 2020 14:12:05
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:18:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:19
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:54:51
User entered '400'	Andryelle Toledo (b) (4)	21 Oct 2020 14:12:05
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:18:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:19
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:54:51
User entered 'mg (mg)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:12:05
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:18:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:19
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:54:51
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 14:12:05
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:18:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:19
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:54:51
User entered 'as needed (PRN)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:12:05
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:18:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:19
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:54:51
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 14:12:05
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:18:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:19
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:54:51
User entered 'Oral (ORAL)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:12:05
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:18:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:19
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:54:51
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 14:12:05
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:19
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:54:51
User entered '08 Oct 2020'	Andryelle Toledo (b) (4)	21 Oct 2020 14:12:05
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:19
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:54:51
User entered '0'	Andryelle Toledo (b) (4)	21 Oct 2020 14:12:05
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:19
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:35:44
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4)	12 Feb 2021 09:34:50
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'update' (Site from DM).	Andryelle Toledo (b) (4)	11 Feb 2021 20:42:07
DataPoint Un-verified.	Andryelle Toledo (b) (4)	11 Feb 2021 20:41:56
User entered 'No (N)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	11 Feb 2021 20:41:56
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 20:15:04
User closed query 'Kindly confirm if medication is ongoing, or if this has ended and update EDC/Source accordingly. Thank you.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 20:35:41
Query 'Kindly confirm if medication is ongoing, or if this has ended and update EDC/Source accordingly. Thank you.' answered with 'Medication is ongoing' (Site from CRA).	Andryelle Toledo (b) (4)	18 Nov 2020 00:58:59
User opened query 'Kindly confirm if medication is ongoing, or if this has ended and update EDC/Source accordingly. Thank you.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 19:10:36
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:54:51
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	21 Oct 2020 14:12:05

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:18:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:19
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:35:46
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Un-verified.	Andryelle Toledo (b) (4)	11 Feb 2021 20:41:56
	(b) (4)	
User entered '12 Oct 2020' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	11 Feb 2021 20:41:56
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:54:51
User entered empty.	Andryelle Toledo (b) (4)	21 Oct 2020 14:12:05
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:18:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:19
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:35:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 04:25:58
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification. ' answered with 'Update' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	29 Jan 2021 22:33:50
DataPoint Un-verified.	Andryelle Toledo (b) (4) (b) (4)	29 Jan 2021 22:33:36
User entered 'No (N)' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	29 Jan 2021 22:33:36

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:18:29

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 08:24:48
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:54:51
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	21 Oct 2020 14:12:05

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:18:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:19
User entered empty.	System	21 Oct 2020 14:12:05

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:19
User entered empty.	System	21 Oct 2020 14:12:05

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:19
User entered empty.	System	21 Oct 2020 14:12:05

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:18:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:27
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 20:49:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 20:49:14
Data point term sent to Coder	System	19 Nov 2020 23:14:19
Coding entries removed.	Andryelle Toledo (b) (4)	19 Nov 2020 23:14:13
	(b) (4)	
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 07:36:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 07:36:01
Data point term sent to Coder	System	18 Nov 2020 01:01:19
User entered 'Prednisone'	Andryelle Toledo (b) (4) (b) (4)	18 Nov 2020 01:00:35

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:18:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:27
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered 'No (N)'	Andryelle Toledo (b) (4)	18 Nov 2020 01:00:35
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:18:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:27
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered 'RASH ON MID BACK (urticaria)'	Andryelle Toledo (b) (4)	19 Nov 2020 23:14:13
reason for change: Data Entry Error	(b) (4)	
User entered 'Rash on Mid back'	Andryelle Toledo (b) (4)	18 Nov 2020 01:00:35
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:18:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:27
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered '20' reason for change: Data Entry Error	Leslie Iverson (b) (4)	18 Nov 2020 17:01:06
	(b) (4)	
User entered '40'	Andryelle Toledo (b) (4)	18 Nov 2020 01:00:35
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:18:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:27
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered 'mg (mg)'	Andryelle Toledo (b) (4)	18 Nov 2020 01:00:35
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:18:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:27
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered empty.	Andryelle Toledo (b) (4)	18 Nov 2020 01:00:35
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:18:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:27
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered 'twice daily (BID)' reason for change:	Leslie Iverson (b) (4)	18 Nov 2020 17:01:06
Data Entry Error	(b) (4)	
User entered 'other (OTHER)'	Andryelle Toledo (b) (4)	18 Nov 2020 01:00:35
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:18:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:27
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered empty; reason for change Data Entry Error	Leslie Iverson (b) (4)	18 Nov 2020 17:01:06
	(b) (4)	
User entered '5 days'	Andryelle Toledo (b) (4)	18 Nov 2020 01:00:35
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:18:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:27
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered 'Oral (ORAL)'	Andryelle Toledo (b) (4)	18 Nov 2020 01:00:35
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:18:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:27
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered empty.	Andryelle Toledo (b) (4)	18 Nov 2020 01:00:35
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:27
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered '13 Nov 2020' reason for change: Data Entry Error	Leslie Iverson (b) (4)	18 Nov 2020 17:01:06
	(b) (4)	
User entered '16 Nov 2020'	Andryelle Toledo (b) (4)	18 Nov 2020 01:00:35
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:27
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered '0'	Andryelle Toledo (b) (4)	18 Nov 2020 01:00:35
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:27
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered 'No (N)' reason for change: New Information	Leslie Iverson (b) (4)	18 Nov 2020 17:01:06
	(b) (4)	
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	18 Nov 2020 01:00:35
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:18:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:27
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered '18 Nov 2020' reason for change: New Information	Andryelle Toledo (b) (4)	19 Nov 2020 23:17:00
	(b) (4)	
User entered '17 Nov 2020' reason for change: New Information	Leslie Iverson (b) (4)	18 Nov 2020 17:01:06
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	18 Nov 2020 01:00:35
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:18:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:27
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered 'No (N)' reason for change: Data Entry Error	Leslie Iverson (b) (4)	18 Nov 2020 17:01:06
	(b) (4)	
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	18 Nov 2020 01:00:35
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:18:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:27
User entered '2'	System	18 Nov 2020 17:01:06
User entered empty.	System	18 Nov 2020 01:00:35

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:27
User entered '1'	System	18 Nov 2020 17:01:06
User entered empty.	System	18 Nov 2020 01:00:35

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:27
User entered '804 (804)'	System	18 Nov 2020 17:01:06
User entered empty.	System	18 Nov 2020 01:00:35

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:18:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:31
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE, PRODUCTSYNONYM: THERAFLU COLD & COUGH NIGHTTIME - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 13:54:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 13:54:35
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
Data point term sent to Coder	System	05 Mar 2021 16:55:36
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 16:54:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Mar 2021 16:54:45
User entered 'THERAFLU MULTISYMPTOM: ACETAMINOPHEN, DYPHENHYDRAMINE HCL, PHENYLEPHRINE HCL' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	05 Mar 2021 16:54:45
Data point term sent to Coder	System	05 Mar 2021 16:54:35
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	05 Mar 2021 16:53:49
Data point term sent to Coder	System	22 Feb 2021 22:20:55
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	22 Feb 2021 22:20:44
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	22 Feb 2021 22:20:30
Data point term sent to Coder	System	19 Nov 2020 23:13:18
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	19 Nov 2020 23:12:41
Comment added 'Line 17 replaces this entry. It was duplicated inadvertently.'	Leslie Iverson (b) (4)	18 Nov 2020 19:46:29
Data point term sent to Coder	System	18 Nov 2020 18:29:39

PRODUCTION RELEASE (v12.003
EAB) (1725)

4140 of 4365

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:18:29

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 18:28:40
User entered empty; reason for change Data Entry Error	Leslie Iverson (b) (4)	18 Nov 2020 18:28:40
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 07:36:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 07:36:02
Data point term sent to Coder	System	18 Nov 2020 01:02:20
User entered 'prednisone'	Andryelle Toledo (b) (4)	18 Nov 2020 01:01:33

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:18:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:31
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	05 Mar 2021 16:53:49
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	22 Feb 2021 22:20:44
	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	22 Feb 2021 22:20:30
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	19 Nov 2020 23:12:41
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Leslie Iverson (b) (4)	18 Nov 2020 18:28:40
	(b) (4)	
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	18 Nov 2020 01:01:33
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:18:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:31
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 19:26:11
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 16:54:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Mar 2021 16:54:45
User entered 'Upper Respiratory infection' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	05 Mar 2021 16:54:45
	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	05 Mar 2021 16:53:49
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	22 Feb 2021 22:20:44
	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	22 Feb 2021 22:20:30
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	19 Nov 2020 23:12:41
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 18:28:40
User entered empty; reason for change Data Entry Error	Leslie Iverson (b) (4)	18 Nov 2020 18:28:40
	(b) (4)	
User entered 'rash on mid back'	Andryelle Toledo (b) (4)	18 Nov 2020 01:01:33
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:18:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:31
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 16:54:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Mar 2021 16:54:45
User entered '1' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	05 Mar 2021 16:54:45
	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	05 Mar 2021 16:53:49
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	22 Feb 2021 22:20:44
	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	22 Feb 2021 22:20:30
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	19 Nov 2020 23:12:41
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 18:28:40
User entered empty; reason for change Data Entry Error	Leslie Iverson (b) (4)	18 Nov 2020 18:28:40
	(b) (4)	
User entered '20'	Andryelle Toledo (b) (4)	18 Nov 2020 01:01:33
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:18:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:31
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 19:26:11
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 16:54:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Mar 2021 16:54:45
User entered 'Other (OTHER)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	05 Mar 2021 16:54:45
	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	05 Mar 2021 16:53:49
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	22 Feb 2021 22:20:44
	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	22 Feb 2021 22:20:30
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	19 Nov 2020 23:12:41
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 18:28:40
User entered empty; reason for change Data Entry Error	Leslie Iverson (b) (4)	18 Nov 2020 18:28:40
	(b) (4)	
User entered 'mg (mg)'	Andryelle Toledo (b) (4)	18 Nov 2020 01:01:33
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:18:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:31
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
User entered 'packet' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	05 Mar 2021 16:54:45
	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	05 Mar 2021 16:53:49
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	22 Feb 2021 22:20:44
	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	22 Feb 2021 22:20:30
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	19 Nov 2020 23:12:41
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	18 Nov 2020 01:01:33
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:18:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:31
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 16:54:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Mar 2021 16:54:45
User entered 'as needed (PRN)' reason for change:	Andryelle Toledo (b) (4)	05 Mar 2021 16:54:45
Data Entry Error	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	05 Mar 2021 16:53:49
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	22 Feb 2021 22:20:44
	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	22 Feb 2021 22:20:30
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	19 Nov 2020 23:12:41
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 18:28:40
User entered empty; reason for change Data Entry Error	Leslie Iverson (b) (4)	18 Nov 2020 18:28:40
	(b) (4)	
User entered 'other (OTHER)'	Andryelle Toledo (b) (4)	18 Nov 2020 01:01:33
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:18:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:31
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	05 Mar 2021 16:53:49
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	22 Feb 2021 22:20:44
	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	22 Feb 2021 22:20:30
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	19 Nov 2020 23:12:41
	(b) (4)	
User entered empty; reason for change Data Entry Error	Leslie Iverson (b) (4)	18 Nov 2020 18:28:40
	(b) (4)	
User entered '5 days'	Andryelle Toledo (b) (4)	18 Nov 2020 01:01:33
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:18:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:31
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 16:54:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Mar 2021 16:54:45
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	05 Mar 2021 16:54:45
	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	05 Mar 2021 16:53:49
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	22 Feb 2021 22:20:44
	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	22 Feb 2021 22:20:30
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	19 Nov 2020 23:12:41
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 19:19:57
User entered empty; reason for change Data Entry Error	Leslie Iverson (b) (4)	18 Nov 2020 19:19:57
	(b) (4)	
User entered 'Oral (ORAL)'	Andryelle Toledo (b) (4)	18 Nov 2020 01:01:33
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:18:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:31
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	05 Mar 2021 16:53:49
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	22 Feb 2021 22:20:44
	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	22 Feb 2021 22:20:30
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	19 Nov 2020 23:12:41
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	18 Nov 2020 01:01:33
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:31
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 19:26:11
	(b) (4)	
User closed query 'Start date is missing and Start date System completely unknown is not checked. Please provide.' (Site from System).		05 Mar 2021 16:54:45
User entered '14 Nov 2020' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	05 Mar 2021 16:54:45
	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	05 Mar 2021 16:53:49
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	22 Feb 2021 22:20:44
	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	22 Feb 2021 22:20:30
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	19 Nov 2020 23:12:41
	(b) (4)	
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	18 Nov 2020 18:28:40
User entered empty; reason for change Data Entry Error	Leslie Iverson (b) (4)	18 Nov 2020 18:28:40
	(b) (4)	
User entered '13 Nov 2020'	Andryelle Toledo (b) (4)	18 Nov 2020 01:01:33
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:18:29

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:31
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	05 Mar 2021 16:53:49
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	22 Feb 2021 22:20:44
	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	22 Feb 2021 22:20:30
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	19 Nov 2020 23:12:41
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	18 Nov 2020 01:01:33
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:31
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	05 Mar 2021 16:53:49
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	22 Feb 2021 22:20:44
	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	22 Feb 2021 22:20:30
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	19 Nov 2020 23:12:41
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Leslie Iverson (b) (4)	18 Nov 2020 18:28:40
	(b) (4)	
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	18 Nov 2020 01:01:33
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:18:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:31
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
	(b) (4)	
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	05 Mar 2021 16:54:45
User entered '19 Nov 2020' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	05 Mar 2021 16:54:45
	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	05 Mar 2021 16:53:49
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	22 Feb 2021 22:20:44
	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	22 Feb 2021 22:20:30
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	19 Nov 2020 23:12:41
	(b) (4)	
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	18 Nov 2020 18:28:40
User entered empty.	Andryelle Toledo (b) (4)	18 Nov 2020 01:01:33
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:18:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:31
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	05 Mar 2021 16:53:49
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	22 Feb 2021 22:20:44
	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	22 Feb 2021 22:20:30
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	19 Nov 2020 23:12:41
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Leslie Iverson (b) (4)	18 Nov 2020 18:28:40
	(b) (4)	
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	18 Nov 2020 01:01:33
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:18:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:31
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	05 Mar 2021 16:53:49
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Andryelle Toledo (b) (4)	22 Feb 2021 22:20:44
	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	22 Feb 2021 22:20:30
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	19 Nov 2020 23:12:41
	(b) (4)	
User entered empty.	System	18 Nov 2020 01:01:33

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:31
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	05 Mar 2021 16:53:49
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	22 Feb 2021 22:20:44
	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	22 Feb 2021 22:20:30
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	19 Nov 2020 23:12:41
	(b) (4)	
User entered empty.	System	18 Nov 2020 01:01:33

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:31
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	05 Mar 2021 16:53:49
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Andryelle Toledo (b) (4)	22 Feb 2021 22:20:44
	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	22 Feb 2021 22:20:30
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	19 Nov 2020 23:12:41
	(b) (4)	
User entered empty.	System	18 Nov 2020 01:01:33

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:18:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Apr 2021 11:59:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 11:59:54
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
Data point term sent to Coder	System	05 Mar 2021 16:56:39
Coding entries removed.	Andryelle Toledo (b) (4)	05 Mar 2021 16:55:49
DataPoint Un-verified.	(b) (4) Andryelle Toledo (b) (4)	05 Mar 2021 16:55:49
Coding entries removed.	(b) (4) Andryelle Toledo (b) (4)	05 Mar 2021 16:55:49
Signature has been broken.	(b) (4) Andryelle Toledo (b) (4)	05 Mar 2021 16:55:49
User entered 'Omeprazole' reason for change: Data Entry Error	(b) (4) Andryelle Toledo (b) (4)	05 Mar 2021 16:55:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:14:49
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL;PHENYLE PHRINE HYDROCHLORIDE, PRODUCTSYNONYM: THERAFLU COLD & COUGH NIGHTTIME - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Nov 2020 10:07:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Nov 2020 10:07:09
Data point term sent to Coder	System	25 Nov 2020 14:56:46

PRODUCTION RELEASE (v12.003
EAB) (1725)

4159 of 4365

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:18:29

Name of Medication

Audit	User	Time (GMT)
User closed query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	System	25 Nov 2020 14:55:50
Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' answered with 'updated' (Site from System).	Leslie Iverson (b) (4)	25 Nov 2020 14:55:50
Data point term sent to Coder	System	25 Nov 2020 14:55:45
DataPoint Un-verified.	Leslie Iverson (b) (4)	25 Nov 2020 14:55:42
User entered 'Acetaminophen, diphenhydramine, phenylephrine (THERAFLU)' reason for change: Data Entry Error	Leslie Iverson (b) (4)	25 Nov 2020 14:55:42
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	23 Nov 2020 08:12:07
Data point term sent to Coder	System	19 Nov 2020 23:09:14
Data point term sent to Coder	System	18 Nov 2020 01:03:20
User entered 'theraflu'	Andryelle Toledo (b) (4)	18 Nov 2020 01:03:02

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:18:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	18 Nov 2020 01:03:02

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:18:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 19:26:11
DataPoint Un-verified.	Andryelle Toledo (b) (4)	05 Mar 2021 16:55:49
	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	05 Mar 2021 16:55:49
	(b) (4)	
User entered 'Worsening of GERD' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	05 Mar 2021 16:55:49
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered 'UPPER RESPIRATORY TRACT INFECTION' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	19 Nov 2020 23:08:34
	(b) (4)	
User entered 'Upper Respiratory Infection'	Andryelle Toledo (b) (4)	18 Nov 2020 01:03:02
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:18:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 19:26:11
DataPoint Un-verified.	Andryelle Toledo (b) (4)	05 Mar 2021 16:55:49
	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	05 Mar 2021 16:55:49
	(b) (4)	
User entered '40' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	05 Mar 2021 16:55:49
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered '1'	Andryelle Toledo (b) (4)	18 Nov 2020 01:03:02
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:18:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 19:26:11
DataPoint Un-verified.		
	Andryelle Toledo (b) (4)	05 Mar 2021 16:55:49
	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	05 Mar 2021 16:55:49
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	05 Mar 2021 16:55:49
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered 'Other (OTHER)'	Andryelle Toledo (b) (4)	18 Nov 2020 01:03:02
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:18:29

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 19:26:11
DataPoint Un-verified.	Andryelle Toledo (b) (4)	05 Mar 2021 16:55:49
	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	05 Mar 2021 16:55:49
	(b) (4)	
User entered empty; reason for change Data Entry Error	Andryelle Toledo (b) (4)	05 Mar 2021 16:55:49
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered 'packet'	Andryelle Toledo (b) (4)	18 Nov 2020 01:03:02
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:18:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 19:26:11
DataPoint Un-verified.	Andryelle Toledo (b) (4)	05 Mar 2021 16:55:49
	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	05 Mar 2021 16:55:49
	(b) (4)	
User entered 'twice daily (BID)' reason for change:	Andryelle Toledo (b) (4)	05 Mar 2021 16:55:49
Data Entry Error	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered 'as needed (PRN)'	Andryelle Toledo (b) (4)	18 Nov 2020 01:03:02
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:18:29

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	18 Nov 2020 01:03:02

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:18:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered 'Oral (ORAL)'	Andryelle Toledo (b) (4) (b) (4)	18 Nov 2020 01:03:02

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:18:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	18 Nov 2020 01:03:02

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 19:26:11
DataPoint Un-verified.	Andryelle Toledo (b) (4)	05 Mar 2021 16:55:49
	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	05 Mar 2021 16:55:49
	(b) (4)	
User entered '12 Nov 2020' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	05 Mar 2021 16:55:49
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
	(b) (4), (b) (6)	
Query 'Per CDM-RQ: Response noted as "Subject have a new UPPER RESPIRATORY TRACT INFECTION", however kindly confirm if this event needs to be updated in AE eCRF as a new entry as it has a different start date, from previously recorded AE#3.Please review and update accordingly or provide clarification.Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 12:18:57
User opened query 'Per CDM-RQ: Response noted as "Subject have a new UPPER RESPIRATORY TRACT INFECTION", however kindly confirm if this event needs to be updated in AE eCRF as a new entry as it has a different start date, from previously recorded AE#3.Please review and update accordingly or provide clarification.Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 13:52:28
User closed query 'Per CDM: Please kindly review and reconcile the Con Med #11 & Con Med #15, and confirm if they are two different events or related events, as in the AE eCRF page, only one AE entry(AE#3) is made with event name of " Upper Respiratory infection", and the corresponding dates are entered, which are matching with that of ConMed 11#. Kindly review and update accordingly or provide clarification. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 13:48:23

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per CDM: Please kindly review and reconcile the Con Med #11 & Con Med #15, and confirm if they are two different events or related events, as in the AE eCRF page, only one AE entry(AE#3) is made with event name of " Upper Respiratory infection", and the corresponding dates are entered, which are matching with that of ConMed 11#. Kindly review and update accordingly or provide clarification. Thank you.' answered with 'Subject have a new UPPER RESPIRATORY TRACT INFECTION' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 23:08:54
User opened query 'Per CDM: Please kindly review and reconcile the Con Med #11 & Con Med #15, and confirm if they are two different events or related events, as in the AE eCRF page, only one AE entry(AE#3) is made with event name of " Upper Respiratory infection", and the corresponding dates are entered, which are matching with that of ConMed 11#. Kindly review and update accordingly or provide clarification. Thank you.' (Site from DM). User entered '14 Nov 2020'	(b) (4), (b) (6) (b) (4) Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 07:25:03 18 Nov 2020 01:03:02

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	18 Nov 2020 01:03:02

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 10:26:50
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'No. Subject is using the dose reported' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	30 Mar 2021 17:17:07
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 15:48:53
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
DataPoint Un-verified.	Andryelle Toledo (b) (4) (b) (4)	05 Mar 2021 16:55:49
Signature has been broken.	Andryelle Toledo (b) (4) (b) (4)	05 Mar 2021 16:55:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	05 Mar 2021 16:55:49
User signature succeeded.	Michael Adams (b) (4) (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:14:59
DataPoint Un-verified.	Leslie Iverson (b) (4) (b) (4)	25 Nov 2020 14:55:42
User entered 'No (N)' reason for change: Data Entry Error	Leslie Iverson (b) (4) (b) (4)	25 Nov 2020 14:55:42
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	18 Nov 2020 01:03:02

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:18:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 19:26:11
DataPoint Un-verified.	Andryelle Toledo (b) (4)	05 Mar 2021 16:55:49
	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	05 Mar 2021 16:55:49
	(b) (4)	
User entered empty; reason for change Data Entry Error	Andryelle Toledo (b) (4)	05 Mar 2021 16:55:49
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:15:01
DataPoint Un-verified.	Leslie Iverson (b) (4)	25 Nov 2020 14:55:42
	(b) (4)	
User entered '19 Nov 2020' reason for change: Data Entry Error	Leslie Iverson (b) (4)	25 Nov 2020 14:55:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered empty.	Andryelle Toledo (b) (4)	18 Nov 2020 01:03:02
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:18:29

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:35:04
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update accordingly or provide clarification. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 13:58:13
Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update accordingly or provide clarification. Thank you.' answered with 'update' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 23:09:08
User entered 'No (N)' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	19 Nov 2020 23:09:03
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update accordingly or provide clarification. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 06:58:35
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	18 Nov 2020 01:03:02

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:18:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Mar 2021 16:55:49
User entered empty.	System	18 Nov 2020 01:03:02

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Mar 2021 16:55:49
User entered empty.	System	18 Nov 2020 01:03:02

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Mar 2021 16:55:49
User entered empty.	System	18 Nov 2020 01:03:02

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:18:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:39
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Mar 2021 16:58:55
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Mar 2021 16:58:55
	(b) (4)	
Data point term sent to Coder	System	05 Mar 2021 16:58:41
Coding entries removed.	Andryelle Toledo (b) (4)	05 Mar 2021 16:58:05
	(b) (4)	
DataPoint Un-verified.	Andryelle Toledo (b) (4)	05 Mar 2021 16:58:05
	(b) (4)	
Coding entries removed.	Andryelle Toledo (b) (4)	05 Mar 2021 16:58:05
	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	05 Mar 2021 16:58:05
	(b) (4)	
User entered 'Prednisone' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	05 Mar 2021 16:58:05
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Dec 2020 11:55:45
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Dec 2020 11:55:45
	(b) (4)	
Data point term sent to Coder	System	21 Dec 2020 22:37:42

PRODUCTION RELEASE (v12.003
EAB) (1725)

4179 of 4365

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:18:29

[Name of Medication](#)

Audit	User	Time (GMT)
Coding entries removed.	Leslie Iverson (b) (4)	21 Dec 2020 22:37:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 01:04:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 01:04:56
Data point term sent to Coder	System	18 Nov 2020 01:04:21
User entered 'Omeprazole'	Andryelle Toledo (b) (4)	18 Nov 2020 01:03:45
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:18:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:39
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered 'No (N)'	Andryelle Toledo (b) (4)	18 Nov 2020 01:03:45
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:18:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:39
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:26:11
DataPoint Un-verified.	Andryelle Toledo (b) (4)	05 Mar 2021 16:58:05
Signature has been broken.	(b) (4) Andryelle Toledo (b) (4)	05 Mar 2021 16:58:05
User entered 'urticaria' reason for change: Data Entry Error	(b) (4) Andryelle Toledo (b) (4)	05 Mar 2021 16:58:05
User signature succeeded.	(b) (4) Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:07:59
DataPoint Un-verified.	(b) (4) Leslie Iverson (b) (4)	21 Dec 2020 22:37:37
User entered 'Worsening of gastroesophageal reflux disease' reason for change: Data Entry Error	(b) (4) Leslie Iverson (b) (4)	21 Dec 2020 22:37:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered 'Acid Reflux'	(b) (4) Andryelle Toledo (b) (4)	18 Nov 2020 01:03:45
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:18:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:39
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
DataPoint Un-verified.	Andryelle Toledo (b) (4)	05 Mar 2021 16:58:05
	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	05 Mar 2021 16:58:05
	(b) (4)	
User entered '20' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	05 Mar 2021 16:58:05
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered '40' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	18 Nov 2020 01:05:09
	(b) (4)	
User entered '20'	Andryelle Toledo (b) (4)	18 Nov 2020 01:03:45
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:18:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:39
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered 'mg (mg)'	Andryelle Toledo (b) (4)	18 Nov 2020 01:03:45
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:18:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:39
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered empty.	Andryelle Toledo (b) (4)	18 Nov 2020 01:03:45
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:18:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:39
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
DataPoint Un-verified.	Andryelle Toledo (b) (4)	05 Mar 2021 16:58:05
	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	05 Mar 2021 16:58:05
	(b) (4)	
User entered 'once daily (QD)' reason for change:	Andryelle Toledo (b) (4)	05 Mar 2021 16:58:05
Data Entry Error	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered 'twice daily (BID)'	Andryelle Toledo (b) (4)	18 Nov 2020 01:03:45
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:18:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:39
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered empty.	Andryelle Toledo (b) (4)	18 Nov 2020 01:03:45
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:18:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:39
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered 'Oral (ORAL)'	Andryelle Toledo (b) (4)	18 Nov 2020 01:03:45
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:18:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:39
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered empty.	Andryelle Toledo (b) (4)	18 Nov 2020 01:03:45
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:39
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
DataPoint Un-verified.	Andryelle Toledo (b) (4)	05 Mar 2021 16:58:05
Signature has been broken.	Andryelle Toledo (b) (4)	05 Mar 2021 16:58:05
User entered '18 Nov 2020' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	05 Mar 2021 16:58:05
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with OMEPRAZOLE, #8 / (Start date UN UNK 2019 - Stop date 12 NOV 2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 09:33:33
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with OMEPRAZOLE, #8 / (Start date UN UNK 2019 - Stop date 12 NOV 2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' answered with 'Subject had dosage update after the AE. ' (Site from DM).	Andryelle Toledo (b) (4)	11 Feb 2021 20:42:46
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with OMEPRAZOLE, #8 / (Start date UN UNK 2019 - Stop date 12 NOV 2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 08:30:00
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered '12 Nov 2020'	Andryelle Toledo (b) (4)	18 Nov 2020 01:03:45

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:39
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered '0'	Andryelle Toledo (b) (4)	18 Nov 2020 01:03:45
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:39
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
	(b) (4)	
DataPoint Un-verified.	Andryelle Toledo (b) (4)	05 Mar 2021 16:58:05
	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	05 Mar 2021 16:58:05
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	05 Mar 2021 16:58:05
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
	(b) (4)	
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	18 Nov 2020 01:03:45
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:18:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:39
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
DataPoint Un-verified.	Andryelle Toledo (b) (4)	05 Mar 2021 16:58:05
	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	05 Mar 2021 16:58:05
	(b) (4)	
User entered '28 Nov 2020' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	05 Mar 2021 16:58:05
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered empty.	Andryelle Toledo (b) (4)	18 Nov 2020 01:03:45
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:18:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:39
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered 'No (N)'	Andryelle Toledo (b) (4)	18 Nov 2020 01:03:45
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:18:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:39
User entered '1'	System	05 Mar 2021 16:58:05
User entered '2'	System	18 Nov 2020 01:03:45

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:39
User entered '1'	System	18 Nov 2020 01:03:45

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:39
User entered '804 (804)'	System	18 Nov 2020 01:03:45

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:18:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:45
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: ANTICHOLINERGICS, PRODUCT: IPRATROPIUM BROMIDE, PRODUCTSYNONYM: ATROVENT - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Mar 2021 04:56:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Mar 2021 04:56:02
Data point term sent to Coder	System	05 Mar 2021 16:59:43
Coding entries removed.	Andryelle Toledo (b) (4)	05 Mar 2021 16:59:06
DataPoint Un-verified.	Andryelle Toledo (b) (4)	05 Mar 2021 16:59:06
Coding entries removed.	Andryelle Toledo (b) (4)	05 Mar 2021 16:59:06
Signature has been broken.	Andryelle Toledo (b) (4)	05 Mar 2021 16:59:06
User entered 'Atrovent' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	05 Mar 2021 16:59:06
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Dec 2020 20:37:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Dec 2020 20:37:11
Data point term sent to Coder	System	07 Dec 2020 23:44:01

PRODUCTION RELEASE (v12.003
EAB) (1725)

4198 of 4365

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:18:29

[Name of Medication](#)

Audit	User	Time (GMT)
Coding entries removed.	Andryelle Toledo (b) (4)	07 Dec 2020 23:43:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 03:43:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 03:43:52
Data point term sent to Coder	System	18 Nov 2020 19:19:01
Data point term sent to Coder	System	18 Nov 2020 17:02:56
User entered 'Prednisone'	Leslie Iverson (b) (4)	18 Nov 2020 17:02:10
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:18:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:45
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered 'No (N)'	Leslie Iverson (b) (4)	18 Nov 2020 17:02:10
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:18:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:45
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
DataPoint Un-verified.	Andryelle Toledo (b) (4)	05 Mar 2021 16:59:06
	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	05 Mar 2021 16:59:06
	(b) (4)	
User entered 'Acute Bronchitis' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	05 Mar 2021 16:59:06
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 20:03:06
User closed query 'Kindly add (urticaria) to indication. Thank you.' (Site from CRA).	(b) (4), (b) (6)	08 Dec 2020 20:03:02
Query 'Kindly add (urticaria) to indication. Thank you.' answered with 'update' (Site from CRA).	Andryelle Toledo (b) (4)	07 Dec 2020 23:43:43
	(b) (4)	
DataPoint Un-verified.	Andryelle Toledo (b) (4)	07 Dec 2020 23:43:37
	(b) (4)	
User entered 'Urticaria' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	07 Dec 2020 23:43:37
	(b) (4)	
User opened query 'Kindly add (urticaria) to indication. Thank you.' (Site from CRA).	(b) (4), (b) (6)	07 Dec 2020 20:15:59
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered 'RASH ON MID BACK' reason for change: Data Entry Error	Leslie Iverson (b) (4)	18 Nov 2020 19:18:18
	(b) (4)	
User entered 'Rash mid back'	Leslie Iverson (b) (4)	18 Nov 2020 17:02:10
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:18:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:45
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
DataPoint Un-verified.	Andryelle Toledo (b) (4)	05 Mar 2021 16:59:06
Signature has been broken.	Andryelle Toledo (b) (4)	05 Mar 2021 16:59:06
User entered '40' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	05 Mar 2021 16:59:06
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Per source it's not clear if the dose is 10 or 20. Kindly confirm this is entered correctly, and ensure source is legible. Thank you.' (Site from CRA).	(b) (4), (b) (6)	07 Dec 2020 20:15:18
Query 'Per source it's not clear if the dose is 10 or 20. Kindly confirm this is entered correctly, and ensure source is legible. Thank you.' answered with 'source corrected and confirmed 20 mg daily' (Site from CRA).	Leslie Iverson (b) (4)	25 Nov 2020 15:00:23
User opened query 'Per source it's not clear if the dose is 10 or 20. Kindly confirm this is entered correctly, and ensure source is legible. Thank you.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 20:37:51
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered '20'	Leslie Iverson (b) (4)	18 Nov 2020 17:02:10

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:18:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:45
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered 'mg (mg)'	Leslie Iverson (b) (4)	18 Nov 2020 17:02:10
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:18:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:45
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered empty.	Leslie Iverson (b) (4)	18 Nov 2020 17:02:10
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:18:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:45
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
DataPoint Un-verified.	Andryelle Toledo (b) (4)	05 Mar 2021 16:59:06
	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	05 Mar 2021 16:59:06
	(b) (4)	
User entered 'as needed (PRN)' reason for change:	Andryelle Toledo (b) (4)	05 Mar 2021 16:59:06
Data Entry Error	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered 'once daily (QD)'	Leslie Iverson (b) (4)	18 Nov 2020 17:02:10
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:18:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:45
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered empty.	Leslie Iverson (b) (4)	18 Nov 2020 17:02:10
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:18:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:45
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
DataPoint Un-verified.	Andryelle Toledo (b) (4)	05 Mar 2021 16:59:06
	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	05 Mar 2021 16:59:06
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	05 Mar 2021 16:59:06
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered 'Oral (ORAL)'	Leslie Iverson (b) (4)	18 Nov 2020 17:02:10
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:18:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:45
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered empty.	Leslie Iverson (b) (4)	18 Nov 2020 17:02:10
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:45
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:26:11
DataPoint Un-verified.	Andryelle Toledo (b) (4)	05 Mar 2021 16:59:06
Signature has been broken.	(b) (4) Andryelle Toledo (b) (4)	05 Mar 2021 16:59:06
User entered '14 Jan 2021' reason for change: Data Entry Error	(b) (4) Andryelle Toledo (b) (4)	05 Mar 2021 16:59:06
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:40:07
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User entered '18 Nov 2020' reason for change: Data Entry Error	(b) (4) Andryelle Toledo (b) (4)	22 Feb 2021 22:19:17
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 21:57:34
User entered '28 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 21:57:34
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered '18 Nov 2020'	Leslie Iverson (b) (4)	18 Nov 2020 17:02:10
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:45
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered '0'	Leslie Iverson (b) (4)	18 Nov 2020 17:02:10
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:45
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:40:07
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Per MM, please provide the end date when available' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 06:13:46
Query 'Per MM, please provide the end date when available' answered with 'update' (Site from DM).	Andryelle Toledo (b) (4)	22 Feb 2021 22:19:29
DataPoint Un-verified.	Andryelle Toledo (b) (4)	22 Feb 2021 22:19:17
User entered 'No (N)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	22 Feb 2021 22:19:17
User opened query 'Per MM, please provide the end date when available' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 11:49:04
User closed query 'Per source this is noted with an end date of 28NOV2020. Kindly update EDC.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 20:10:17
Query 'Per source this is noted with an end date of 28NOV2020. Kindly update EDC.' answered with 'has been updated' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 21:58:05
User opened query 'Per source this is noted with an end date of 28NOV2020. Kindly update EDC.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 19:55:21
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered 'Yes (Y)'	Leslie Iverson (b) (4)	18 Nov 2020 17:02:10

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:18:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:45
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:26:11
DataPoint Un-verified.	Andryelle Toledo (b) (4)	05 Mar 2021 16:59:06
Signature has been broken.	(b) (4) Andryelle Toledo (b) (4)	05 Mar 2021 16:59:06
User entered '20 Jan 2021' reason for change: Data Entry Error	(b) (4) Andryelle Toledo (b) (4)	05 Mar 2021 16:59:06
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:40:07
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Future date has been entered. Please correct.' (Site from System).	(b) (4) System	22 Feb 2021 22:19:22
User entered '28 Nov 2020' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	22 Feb 2021 22:19:22
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	22 Feb 2021 22:19:17
DataPoint Un-verified.	Andryelle Toledo (b) (4) (b) (4)	22 Feb 2021 22:19:17
User entered '28 Nov 2021' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	22 Feb 2021 22:19:17
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered empty.	Leslie Iverson (b) (4) (b) (4)	18 Nov 2020 17:02:10

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:18:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:45
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:35:04
User entered 'No (N)'	Leslie Iverson (b) (4)	18 Nov 2020 17:02:10
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:18:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:45
User entered empty.	System	05 Mar 2021 16:59:06
User entered '1'	System	18 Nov 2020 17:02:10

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:45
User entered empty.	System	05 Mar 2021 16:59:06
User entered '1'	System	18 Nov 2020 17:02:10

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:45
User entered empty.	System	05 Mar 2021 16:59:06
User entered '804 (804)'	System	18 Nov 2020 17:02:10

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:18:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Jan 2021 23:41:59
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Jan 2021 23:41:59
	(b) (4)	
Data point term sent to Coder	System	14 Jan 2021 23:23:11
User entered 'Doxycycline'	Leslie Iverson (b) (4)	14 Jan 2021 23:22:24
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:18:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered 'No (N)'	Leslie Iverson (b) (4)	14 Jan 2021 23:22:24
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:18:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered 'Acute Sinusitis'	Leslie Iverson (b) (4)	14 Jan 2021 23:22:24
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:18:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered '100'	Leslie Iverson (b) (4)	14 Jan 2021 23:22:24
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:18:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered 'mg (mg)'	Leslie Iverson (b) (4)	14 Jan 2021 23:22:24
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:18:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered empty.	Leslie Iverson (b) (4)	14 Jan 2021 23:22:24
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:18:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered 'twice daily (BID)'	Leslie Iverson (b) (4)	14 Jan 2021 23:22:24
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:18:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered empty.	Leslie Iverson (b) (4)	14 Jan 2021 23:22:24
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:18:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered 'Oral (ORAL)'	Leslie Iverson (b) (4)	14 Jan 2021 23:22:24
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:18:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered empty.	Leslie Iverson (b) (4)	14 Jan 2021 23:22:24
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered '13 Jan 2021'	Leslie Iverson (b) (4)	14 Jan 2021 23:22:24
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered '0'	Leslie Iverson (b) (4)	14 Jan 2021 23:22:24
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:09
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:37:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 22:29:53
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	25 Jan 2021 22:29:53
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered 'Yes (Y)'	Leslie Iverson (b) (4)	14 Jan 2021 23:22:24
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:18:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:09
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:38:40
	(b) (4)	
User closed query 'Per source this is noted as 22JAN2021, Kindly update EDC.' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 15:38:38
Query 'Per source this is noted as 22JAN2021, Kindly update EDC.' answered with 'Update' (Site from CRA).	Andryelle Toledo (b) (4)	18 Mar 2021 18:09:39
	(b) (4)	
DataPoint Un-verified.	Andryelle Toledo (b) (4)	18 Mar 2021 18:09:33
	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	18 Mar 2021 18:09:33
	(b) (4)	
User entered '22 Jan 2021' reason for change: New Information	Andryelle Toledo (b) (4)	18 Mar 2021 18:09:33
	(b) (4)	
User opened query 'Per source this is noted as 22JAN2021, Kindly update EDC.' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 19:27:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:37:11
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 22:29:53
	(b) (4)	
User entered '20 Jan 2021' reason for change: New Information	(b) (4), (b) (6)	25 Jan 2021 22:29:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
	(b) (4)	
User entered empty.	Leslie Iverson (b) (4)	14 Jan 2021 23:22:24
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:18:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered 'No (N)'	Leslie Iverson (b) (4)	14 Jan 2021 23:22:24
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:18:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:09
User entered '2'	System	14 Jan 2021 23:22:24

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:09
User entered '1'	System	14 Jan 2021 23:22:24

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:09
User entered '804 (804)'	System	14 Jan 2021 23:22:24

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:18:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:11
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS AND EXPECTORANTS, COMBINATIONS, ATC: OPIUM DERIVATIVES AND EXPECTORANTS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN, PRODUCTSYNONYM: MUCINEX DM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 14:28:43
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 14:28:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
Data point term sent to Coder	System	05 Mar 2021 17:02:45
Coding entries removed.	Andryelle Toledo (b) (4)	05 Mar 2021 17:01:55
	(b) (4)	
DataPoint Un-verified.	Andryelle Toledo (b) (4)	05 Mar 2021 17:01:55
	(b) (4)	
Coding entries removed.	Andryelle Toledo (b) (4)	05 Mar 2021 17:01:55
	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	05 Mar 2021 17:01:55
	(b) (4)	
User entered 'Mucinex DM(Dextromethorphan HBr - Guaifenesin)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	05 Mar 2021 17:01:55
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: ANTICHOLINERGICS, PRODUCT: IPRATROPIUM BROMIDE, PRODUCTSYNONYM: ATROVENT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Jan 2021 23:25:59
	(b) (4)	

PRODUCTION RELEASE (v12.003
EAB) (1725)

4235 of 4365

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:18:29

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder	Coder Import (b) (4)	14 Jan 2021 23:25:59
User entered 'Atrovent Metered Dose Inhaler'	System Leslie Iverson (b) (4)	14 Jan 2021 23:24:13 14 Jan 2021 23:23:32

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:18:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:11
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered 'No (N)'	Leslie Iverson (b) (4)	14 Jan 2021 23:23:32
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:18:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:11
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
DataPoint Un-verified.	Andryelle Toledo (b) (4)	05 Mar 2021 17:01:55
	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	05 Mar 2021 17:01:55
	(b) (4)	
User entered 'ACUTE Sinusitis' reason for change:	Andryelle Toledo (b) (4)	05 Mar 2021 17:01:55
Data Entry Error	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered 'Acute Bronchitis'	Leslie Iverson (b) (4)	14 Jan 2021 23:23:32
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:18:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:11
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
DataPoint Un-verified.	Andryelle Toledo (b) (4)	05 Mar 2021 17:01:55
Signature has been broken.	Andryelle Toledo (b) (4)	05 Mar 2021 17:01:55
User entered '60-1200' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	05 Mar 2021 17:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 09:35:04
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'Subject is using 2 puff each puff have 20 mcg. ' (Site from DM).	Andryelle Toledo (b) (4)	11 Feb 2021 20:45:10
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 20:33:01
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered '40'	Leslie Iverson (b) (4)	14 Jan 2021 23:23:32

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:18:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:11
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
DataPoint Un-verified.	Andryelle Toledo (b) (4)	05 Mar 2021 17:01:55
Signature has been broken.	Andryelle Toledo (b) (4)	05 Mar 2021 17:01:55
User entered 'mg (mg)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	05 Mar 2021 17:01:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:40:07
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
User closed query 'Per CDM: Dose unit was recorded as Other and If dose unit is Other, specify was recorded as 'MCG'. However, instead of entering Other-MCG, if appropriate please consider selecting 'µg' from available options in Dose unit field. Thank you. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 03:22:18
Query 'Per CDM: Dose unit was recorded as Other and If dose unit is Other, specify was recorded as 'MCG'. However, instead of entering Other-MCG, if appropriate please consider selecting 'µg' from available options in Dose unit field. Thank you. ' answered with 'has been updated' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 22:21:00
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	21 Jan 2021 22:20:46
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	21 Jan 2021 22:11:56
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 22:11:56
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 22:11:56
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:18:29

[Dose unit](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Dose unit was recorded as Other and If dose unit is Other, specify was recorded as 'MCG'. However, instead of entering Other-MCG, if appropriate please consider selecting 'µg' from available options in Dose unit field. Thank you. ' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 09:58:52
User entered 'Other (OTHER)'	Leslie Iverson (b) (4)	14 Jan 2021 23:23:32

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:18:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:11
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:37:23
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 22:20:46
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 22:20:46
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered 'mcg'	Leslie Iverson (b) (4)	14 Jan 2021 23:23:32
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:18:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:11
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered 'as needed (PRN)'	Leslie Iverson (b) (4)	14 Jan 2021 23:23:32
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:18:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:11
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered empty.	Leslie Iverson (b) (4)	14 Jan 2021 23:23:32
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:18:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:11
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
	(b) (4)	
DataPoint Un-verified.	Andryelle Toledo (b) (4)	05 Mar 2021 17:01:55
	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	05 Mar 2021 17:01:55
	(b) (4)	
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	05 Mar 2021 17:01:55
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Leslie Iverson (b) (4)	14 Jan 2021 23:23:32
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:18:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:11
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered empty.	Leslie Iverson (b) (4)	14 Jan 2021 23:23:32
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:11
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
DataPoint Un-verified.	Andryelle Toledo (b) (4)	05 Mar 2021 17:01:55
	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	05 Mar 2021 17:01:55
	(b) (4)	
User entered '15 Jan 2021' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	05 Mar 2021 17:01:55
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered '14 Jan 2021'	Leslie Iverson (b) (4)	14 Jan 2021 23:23:32
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:11
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered '0'	Leslie Iverson (b) (4)	14 Jan 2021 23:23:32
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:11
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:37:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 22:29:28
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	25 Jan 2021 22:29:28
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered 'Yes (Y)'	Leslie Iverson (b) (4)	14 Jan 2021 23:23:32
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:18:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:11
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
	(b) (4)	
User closed query 'Per source the end date is noted as 20JAN2021, kindly update EDC accordingly. Thank you.' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 15:06:18
User entered '22 Jan 2021' reason for change: New Information	Andryelle Toledo (b) (4)	05 Mar 2021 17:01:55
	(b) (4)	
Query 'Per source the end date is noted as 20JAN2021, kindly update EDC accordingly. Thank you.' answered with 'update' (Site from CRA).	Andryelle Toledo (b) (4)	03 Mar 2021 16:54:18
	(b) (4)	
DataPoint Un-verified.	Andryelle Toledo (b) (4)	03 Mar 2021 16:54:11
	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	03 Mar 2021 16:54:11
	(b) (4)	
User entered '20 Jan 2021' reason for change: New Information	Andryelle Toledo (b) (4)	03 Mar 2021 16:54:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:38:25
	(b) (4)	
User opened query 'Per source the end date is noted as 20JAN2021, kindly update EDC accordingly. Thank you.' (Site from CRA).	(b) (4), (b) (6)	02 Mar 2021 21:38:18
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 22:29:28
	(b) (4)	
User entered '22 Jan 2021' reason for change: New Information	(b) (4), (b) (6)	25 Jan 2021 22:29:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
	(b) (4)	
User entered empty.	Leslie Iverson (b) (4)	14 Jan 2021 23:23:32
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:18:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:11
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Jan 2021 21:55:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Jan 2021 21:55:45
User entered 'No (N)' reason for change: Data Entry Error	Leslie Iverson (b) (4)	15 Jan 2021 21:55:45
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Jan 2021 23:23:32
User entered empty.	Leslie Iverson (b) (4)	14 Jan 2021 23:23:32
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:18:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:11
User entered empty.	System	14 Jan 2021 23:23:32

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:11
User entered empty.	System	14 Jan 2021 23:23:32

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:11
User entered empty.	System	14 Jan 2021 23:23:32

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:18:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:17
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFTRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 17:04:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 17:04:11
Data point term sent to Coder	System	05 Mar 2021 17:03:48
Coding entries removed.	Andryelle Toledo (b) (4)	05 Mar 2021 17:03:00
	(b) (4)	
DataPoint Un-verified.	Andryelle Toledo (b) (4)	05 Mar 2021 17:03:00
	(b) (4)	
Coding entries removed.	Andryelle Toledo (b) (4)	05 Mar 2021 17:03:00
	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	05 Mar 2021 17:03:00
	(b) (4)	
User entered 'Zofran' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	05 Mar 2021 17:03:00
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:18:29

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS AND EXPECTORANTS, COMBINATIONS, ATC: OPIUM DERIVATIVES AND EXPECTORANTS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN, PRODUCTSYNONYM: MUCINEX DM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Jan 2021 13:16:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Jan 2021 13:16:15
Data point term sent to Coder	System	15 Jan 2021 22:44:24
User entered 'Mucinex DM (Guaifenesin 1200mg and Dextromethorphan 60mg)'	Leslie Iverson (b) (4)	15 Jan 2021 22:44:13

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:18:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered 'No (N)'	Leslie Iverson (b) (4)	15 Jan 2021 22:44:13
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:18:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:17
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
	(b) (4)	
DataPoint Un-verified.	Andryelle Toledo (b) (4)	05 Mar 2021 17:03:00
	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	05 Mar 2021 17:03:00
	(b) (4)	
User entered 'nausea' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	05 Mar 2021 17:03:00
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
	(b) (4)	
User entered 'Acute Sinusitis'	Leslie Iverson (b) (4)	15 Jan 2021 22:44:13
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:18:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:17
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
DataPoint Un-verified.	Andryelle Toledo (b) (4)	05 Mar 2021 17:03:00
	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	05 Mar 2021 17:03:00
	(b) (4)	
User entered '4' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	05 Mar 2021 17:03:00
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered '1'	Leslie Iverson (b) (4)	15 Jan 2021 22:44:13
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:18:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:17
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
DataPoint Un-verified.	Andryelle Toledo (b) (4)	05 Mar 2021 17:03:00
	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	05 Mar 2021 17:03:00
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	05 Mar 2021 17:03:00
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered 'tablet (TABLET)'	Leslie Iverson (b) (4)	15 Jan 2021 22:44:13
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:18:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 22:44:13
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:18:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered 'as needed (PRN)'	Leslie Iverson (b) (4)	15 Jan 2021 22:44:13
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:18:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 22:44:13
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:18:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered 'Oral (ORAL)'	Leslie Iverson (b) (4)	15 Jan 2021 22:44:13
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:18:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 22:44:13
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:17
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
	(b) (4)	
DataPoint Un-verified.	Andryelle Toledo (b) (4)	05 Mar 2021 17:03:00
	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	05 Mar 2021 17:03:00
	(b) (4)	
User entered '11 Jan 2021' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	05 Mar 2021 17:03:00
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
	(b) (4)	
User entered '15 Jan 2021'	Leslie Iverson (b) (4)	15 Jan 2021 22:44:13
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:17
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered '0'	Leslie Iverson (b) (4)	15 Jan 2021 22:44:13
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:17
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:40:07
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 22:29:07
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	25 Jan 2021 22:29:07
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered 'Yes (Y)'	Leslie Iverson (b) (4)	15 Jan 2021 22:44:13
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:18:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:17
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 19:26:11
DataPoint Un-verified.	Andryelle Toledo (b) (4)	05 Mar 2021 17:03:00
	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	05 Mar 2021 17:03:00
	(b) (4)	
User entered '13 Jan 2021' reason for change: New Information	Andryelle Toledo (b) (4)	05 Mar 2021 17:03:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:40:07
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 22:29:07
	(b) (4)	
User entered '22 Jan 2021' reason for change: New Information	(b) (4), (b) (6)	25 Jan 2021 22:29:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
	(b) (4)	
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 22:44:13
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:18:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:17
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:40:07
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Feb 2021 20:45:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Feb 2021 20:45:36
DataPoint Un-verified.	Andryelle Toledo (b) (4)	11 Feb 2021 20:45:36
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	11 Feb 2021 20:45:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Jan 2021 22:44:13
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 22:44:13
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:18:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:17
User entered empty.	System	15 Jan 2021 22:44:13

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:17
User entered empty.	System	15 Jan 2021 22:44:13

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:17
User entered empty.	System	15 Jan 2021 22:44:13

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:18:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:21
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med name, # 11 / (Start date 29 SEP 2020- Stop date 12 OCT 2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 10:28:15
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med name, # 11 / (Start date 29 SEP 2020- Stop date 12 OCT 2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' answered with 'I confirm medication and dates.' (Site from DM).	Andryelle Toledo (b) (4)	30 Mar 2021 17:46:29
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med name, # 11 / (Start date 29 SEP 2020- Stop date 12 OCT 2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 15:49:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL;PHENYLE PHRINE HYDROCHLORIDE, PRODUCTSYNONYM: THERAFLU COLD & COUGH NIGHTTIME - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 13:55:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 13:55:34
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
Data point term sent to Coder	System	05 Mar 2021 17:06:53

PRODUCTION RELEASE (v12.003
EAB) (1725)

4274 of 4365

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:18:29

Name of Medication

Audit	User	Time (GMT)
Coding entries removed.	Andryelle Toledo (b) (4)	05 Mar 2021 17:06:29
DataPoint Un-verified.	Andryelle Toledo (b) (4)	05 Mar 2021 17:06:29
Coding entries removed.	Andryelle Toledo (b) (4)	05 Mar 2021 17:06:29
Signature has been broken.	Andryelle Toledo (b) (4)	05 Mar 2021 17:06:29
User entered 'THERAFLU MULTISYMPOM: ACETAMINOPHEN, DYPHENHYDRAMINE HCL, PHENYLEPHRINE HCL' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	05 Mar 2021 17:06:29
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Jan 2021 22:46:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Jan 2021 22:46:00
Data point term sent to Coder	System	15 Jan 2021 22:45:27
User entered 'Zofran'	Leslie Iverson (b) (4)	15 Jan 2021 22:45:20

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:18:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered 'No (N)'	Leslie Iverson (b) (4)	15 Jan 2021 22:45:20
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:18:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:21
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
DataPoint Un-verified.	Andryelle Toledo (b) (4)	05 Mar 2021 17:06:29
	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	05 Mar 2021 17:06:29
	(b) (4)	
User entered 'Myalgia and Arthralgia' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	05 Mar 2021 17:06:29
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered 'Nausea'	Leslie Iverson (b) (4)	15 Jan 2021 22:45:20
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:18:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:21
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
DataPoint Un-verified.	Andryelle Toledo (b) (4)	05 Mar 2021 17:06:29
	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	05 Mar 2021 17:06:29
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	05 Mar 2021 17:06:29
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered '4'	Leslie Iverson (b) (4)	15 Jan 2021 22:45:20
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:18:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:21
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
	(b) (4)	
DataPoint Un-verified.	Andryelle Toledo (b) (4)	05 Mar 2021 17:06:29
	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	05 Mar 2021 17:06:29
	(b) (4)	
User entered 'Other (OTHER)' reason for change:	Andryelle Toledo (b) (4)	05 Mar 2021 17:06:29
Data Entry Error	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
	(b) (4)	
User entered 'mg (mg)'	Leslie Iverson (b) (4)	15 Jan 2021 22:45:20
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:18:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:21
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
	(b) (4)	
DataPoint Un-verified.	Andryelle Toledo (b) (4)	05 Mar 2021 17:06:29
	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	05 Mar 2021 17:06:29
	(b) (4)	
User entered 'packet' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	05 Mar 2021 17:06:29
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
	(b) (4)	
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 22:45:20
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:18:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered 'as needed (PRN)'	Leslie Iverson (b) (4)	15 Jan 2021 22:45:20
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:18:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 22:45:20
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:18:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered 'Oral (ORAL)'	Leslie Iverson (b) (4)	15 Jan 2021 22:45:20
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:18:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 22:45:20
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:21
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
User entered '29 Sep 2020' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	05 Mar 2021 17:06:29
	(b) (4)	
DataPoint Un-verified.	Andryelle Toledo (b) (4)	03 Mar 2021 16:57:01
	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	03 Mar 2021 16:57:01
	(b) (4)	
User entered '11 Jan 2021' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	03 Mar 2021 16:57:01
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered '15 Jan 2021'	Leslie Iverson (b) (4)	15 Jan 2021 22:45:20
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User entered '0'	Leslie Iverson (b) (4)	15 Jan 2021 22:45:20
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:21
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 19:26:11
User closed query 'Per source the end date for this con med is noted as 13JAN2021, kindly update EDC. Thank you.' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 15:06:32
Query 'Per source the end date for this con med is noted as 13JAN2021, kindly update EDC. Thank you.' answered with 'update' (Site from CRA).	Andryelle Toledo (b) (4)	03 Mar 2021 16:55:06
DataPoint Un-verified.	(b) (4)	
	Andryelle Toledo (b) (4)	03 Mar 2021 16:54:45
Signature has been broken.	(b) (4)	
	Andryelle Toledo (b) (4)	03 Mar 2021 16:54:45
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	03 Mar 2021 16:54:45
	(b) (4)	
User opened query 'Per source the end date for this con med is noted as 13JAN2021, kindly update EDC. Thank you.' (Site from CRA).	(b) (4), (b) (6)	02 Mar 2021 21:39:52
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
	(b) (4)	
User entered 'Yes (Y)'	Leslie Iverson (b) (4)	15 Jan 2021 22:45:20
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:18:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:21
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:26:11
	(b) (4)	
User entered '10 Oct 2020' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	05 Mar 2021 17:06:29
	(b) (4)	
User closed query 'End date is prior to start date. Please correct.' (Site from System).	System	03 Mar 2021 16:57:01
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	03 Mar 2021 16:54:45
DataPoint Un-verified.	Andryelle Toledo (b) (4)	03 Mar 2021 16:54:45
	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	03 Mar 2021 16:54:45
	(b) (4)	
User entered '13 Jan 2021' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	03 Mar 2021 16:54:45
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
	(b) (4)	
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 22:45:20
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:18:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:55:33
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Jan 2021 22:46:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Jan 2021 22:46:32
User entered 'No (N)' reason for change: Data Entry Error	Leslie Iverson (b) (4)	15 Jan 2021 22:46:32
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Jan 2021 22:45:20
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 22:45:20
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:18:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:21
User entered empty.	System	15 Jan 2021 22:45:20

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:21
User entered empty.	System	15 Jan 2021 22:45:20

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:21
User entered empty.	System	15 Jan 2021 22:45:20

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:18:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:57:14
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: DURAPATITE, PRODUCTSYNONYM: RADIESSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Mar 2021 05:29:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	05 Mar 2021 05:29:47
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:40:07
Data point term sent to Coder	System	01 Mar 2021 23:58:18
User entered 'Radiesse'	Courtney Jensen (b) (4)	01 Mar 2021 23:57:37
	(b) (4)	

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:18:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:57:14
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:40:07
User entered 'No (N)'	Courtney Jensen (b) (4)	01 Mar 2021 23:57:37

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:18:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:57:14
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:40:07
User entered 'Elective'	Courtney Jensen (b) (4)	01 Mar 2021 23:57:37

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:18:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:57:14
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:40:07
User entered '0.8'	Courtney Jensen (b) (4)	01 Mar 2021 23:57:37

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:18:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:57:14
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:40:07
User entered 'mL (mL)'	Courtney Jensen (b) (4)	01 Mar 2021 23:57:37

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:18:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:57:14
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:40:07
User entered empty.	Courtney Jensen (b) (4)	01 Mar 2021 23:57:37

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:18:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:57:14
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:40:07
User entered 'once (ONCE)'	Courtney Jensen (b) (4)	01 Mar 2021 23:57:37

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:18:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:57:14
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:40:07
User entered empty.	Courtney Jensen (b) (4)	01 Mar 2021 23:57:37

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:18:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:57:14
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:40:07
User entered 'Transdermal (TRANSDERMAL)'	Courtney Jensen (b) (4)	01 Mar 2021 23:57:37

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:18:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:57:14
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:40:07
User entered empty.	Courtney Jensen (b) (4)	01 Mar 2021 23:57:37

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:57:14
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:40:07
User entered 'un UNK 2019'	Courtney Jensen (b) (4)	01 Mar 2021 23:57:37

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:57:14
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:40:07
User entered '0'	Courtney Jensen (b) (4)	01 Mar 2021 23:57:37

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:57:14
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:40:07
User entered 'No (N)'	Courtney Jensen (b) (4)	01 Mar 2021 23:57:37

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:18:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:57:14
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:40:07
User entered 'un UNK 2019'	Courtney Jensen (b) (4)	01 Mar 2021 23:57:37

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:18:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:57:14
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:40:07
User entered 'No (N)'	Courtney Jensen (b) (4)	01 Mar 2021 23:57:37

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:18:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:57:14
User entered empty.	System	01 Mar 2021 23:57:37

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:57:14
User entered empty.	System	01 Mar 2021 23:57:37

US3892032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:18:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:57:14
User entered empty.	System	01 Mar 2021 23:57:37

US3892032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:18:29

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:54:30
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:10:34
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:41:11
DataPoint Un-verified.	Leslie Iverson (b) (4)	18 Nov 2020 17:25:35
User entered 'Yes (Y)' reason for change: Data Entry Error	Leslie Iverson (b) (4)	18 Nov 2020 17:25:35
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:10:51
User entered 'No (N)'	chase Carnahan (b) (4)	31 Aug 2020 22:01:45

US3892032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:18:29

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 19:57:33
User closed query 'Kindly to locate date of procedure in source, kindly provide. ' (Site from CRA).	(b) (4), (b) (6)	14 Jan 2021 17:09:18
Query 'Kindly to locate date of procedure in source, kindly provide. ' answered with 'update' (Site from CRA).	Andryelle Toledo (b) (4)	13 Jan 2021 18:07:03
	(b) (4)	
User opened query 'Kindly to locate date of procedure in source, kindly provide. ' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 19:09:04
User entered '24 Sep 2020'	Leslie Iverson (b) (4)	18 Nov 2020 17:26:31
	(b) (4)	

US3892032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:18:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:57:33
User entered 'Routine Dental Cleaning'	Leslie Iverson (b) (4) (b) (4)	18 Nov 2020 17:26:31

US3892032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:18:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:57:33
User entered 'Other (OTHER)'	Leslie Iverson (b) (4) (b) (4)	18 Nov 2020 17:26:31

US3892032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:18:29

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 19:57:33
User closed query 'Per source, barrium swallow was performed on 10NOV2020. Kindly add to EDC. ' (Site from CRA).	(b) (4), (b) (6)	14 Jan 2021 17:09:21
Query 'Per source, barrium swallow was performed on 10NOV2020. Kindly add to EDC. ' answered with 'update' (Site from CRA).	Andryelle Toledo (b) (4)	14 Jan 2021 01:33:37
	(b) (4)	
User opened query 'Per source, barrium swallow was performed on 10NOV2020. Kindly add to EDC. ' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 19:09:40
User entered 'Dental Prophylaxis'	Leslie Iverson (b) (4)	18 Nov 2020 17:26:31
	(b) (4)	

US3892032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:18:29

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:57:33
User entered '10 Nov 2020'	Andryelle Toledo (b) (4) (b) (4)	13 Jan 2021 18:07:27

US3892032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:18:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 21:41:29
User closed query 'Per DM CLR: Please review and confirm this recorded term as it does not appear to be a surgery or procedure. Review and ensure that only procedure or surgery are recorded in this form. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 12:32:31
Query 'Per DM CLR: Please review and confirm this recorded term as it does not appear to be a surgery or procedure. Review and ensure that only procedure or surgery are recorded in this form. Update eCRF as appropriate.' answered with 'update' (Site from DM).	Andryelle Toledo (b) (4)	24 Feb 2021 17:03:12
DataPoint Un-verified.	(b) (4)	
	Andryelle Toledo (b) (4)	24 Feb 2021 17:02:59
User entered 'Barium Swallow' reason for change:	(b) (4)	
Data Entry Error	Andryelle Toledo (b) (4)	24 Feb 2021 17:02:59
	(b) (4)	
User opened query 'Per DM CLR: Please review and confirm this recorded term as it does not appear to be a surgery or procedure. Review and ensure that only procedure or surgery are recorded in this form. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Feb 2021 01:15:48
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:57:33
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 18:07:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Jan 2021 18:07:53
User entered 'Acid Reflux - Gastroesophageal reflux disease' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	13 Jan 2021 18:07:53
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 18:07:27
User entered empty.	Andryelle Toledo (b) (4)	13 Jan 2021 18:07:27
	(b) (4)	

US3892032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:18:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 21:41:32
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	24 Feb 2021 17:03:14
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	24 Feb 2021 17:02:59
DataPoint Un-verified.	Andryelle Toledo (b) (4)	24 Feb 2021 17:02:59
	(b) (4)	
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	24 Feb 2021 17:02:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:57:33
User entered 'Medical History (MH)'	Andryelle Toledo (b) (4)	13 Jan 2021 18:07:27
	(b) (4)	

US3892032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:18:29

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 21:41:35
User entered empty; reason for change Data Entry Error	Andryelle Toledo (b) (4)	24 Feb 2021 17:03:14
DataPoint Un-verified.	(b) (4)	
	Andryelle Toledo (b) (4)	24 Feb 2021 17:02:59
	(b) (4)	
User entered 'ACID REFLUX - GASTROESOPHAGEAL REFLUX DISEASE' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	24 Feb 2021 17:02:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:57:33
User entered empty.	Andryelle Toledo (b) (4)	13 Jan 2021 18:07:27
	(b) (4)	

US3892032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:18:29

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 19:57:33
User entered '13 Jan 2021'	Leslie Iverson (b) (4)	14 Jan 2021 23:15:38
	(b) (4)	

US3892032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:18:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:57:33
User entered 'Chest X-ray'	Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:15:38

US3892032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:18:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:57:33
User entered 'Adverse Event (AE)'	Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:15:38

US3892032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:18:29

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:57:33
User entered empty.	Leslie Iverson (b) (4) (b) (4)	14 Jan 2021 23:15:38

US3892032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:18:29

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:57
	(b) (4)	
User entered '05 Apr 2021'	Rachel Law (b) (4)	23 Apr 2021 21:31:05
	(b) (4)	

US3892032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:18:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:57
	(b) (4)	
User entered 'MRI left knee'	Rachel Law (b) (4)	23 Apr 2021 21:31:05
	(b) (4)	

US3892032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:18:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:57
	(b) (4)	
User entered 'Adverse Event (AE)'	Rachel Law (b) (4)	23 Apr 2021 21:31:05
	(b) (4)	

US3892032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:18:29

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:57
	(b) (4)	
User entered empty.	Rachel Law (b) (4)	23 Apr 2021 21:31:05
	(b) (4)	

US3892032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:18:29

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:57
	(b) (4)	
User entered '22 Apr 2021'	Rachel Law (b) (4)	23 Apr 2021 21:31:23
	(b) (4)	

US3892032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:18:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:57
	(b) (4)	
User entered 'surgical repair left foot'	Rachel Law (b) (4)	23 Apr 2021 21:31:23
	(b) (4)	

US3892032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:18:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:57
	(b) (4)	
User entered 'Adverse Event (AE)'	Rachel Law (b) (4)	23 Apr 2021 21:31:23
	(b) (4)	

US3892032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:18:29

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:57
	(b) (4)	
User entered empty.	Rachel Law (b) (4)	23 Apr 2021 21:31:23
	(b) (4)	

US3892032

Folder: SAE USA-US209-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:25:37
User entered 'USA-US209-2021-MRNA-1273-P301000005'	System	26 Apr 2021 17:15:03

US3892032

Folder: SAE USA-US209-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:25:37
User entered 'Yes (Y)'	System	26 Apr 2021 17:15:03

US3892032

Folder: SAE USA-US209-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:29

Death

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:25:37
User entered 'No (N)'	System	26 Apr 2021 17:15:03

US3892032

Folder: SAE USA-US209-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:25:37
User entered 'No (N)'	System	26 Apr 2021 17:15:03

US3892032

Folder: SAE USA-US209-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:25:37
User entered 'Yes (Y)'	System	26 Apr 2021 17:15:03

US3892032

Folder: SAE USA-US209-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:25:37
User entered 'No (N)'	System	26 Apr 2021 17:15:03

US3892032

Folder: SAE USA-US209-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:25:37
User entered 'No (N)'	System	26 Apr 2021 17:15:03

US3892032

Folder: SAE USA-US209-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:25:37
User entered 'No (N)'	System	26 Apr 2021 17:15:03

US3892032

Folder: SAE USA-US209-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:25:37
User entered 'Michael'	System	26 Apr 2021 17:15:03

US3892032

Folder: SAE USA-US209-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:25:37
User entered 'Adams'	System	26 Apr 2021 17:15:03

US3892032

Folder: SAE USA-US209-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:29

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:25:37
User entered '5251 S Green St'	System	26 Apr 2021 17:15:03

US3892032

Folder: SAE USA-US209-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:29

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:25:37
User entered 'Murray'	System	26 Apr 2021 17:15:03

US3892032

Folder: SAE USA-US209-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:29

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:25:37
User entered 'UT'	System	26 Apr 2021 17:15:03

US3892032

Folder: SAE USA-US209-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:25:37
User entered '84123'	System	26 Apr 2021 17:15:03

US3892032

Folder: SAE USA-US209-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:57
User entered 'US'	(b) (4) System	26 Apr 2021 18:25:42

US3892032

Folder: SAE USA-US209-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Apr 2021 18:25:42

US3892032

Folder: SAE USA-US209-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:25:37
User entered 'USA-US209-2021-MRNA-1273-P301000005'	System	26 Apr 2021 17:15:03

US3892032

Folder: SAE USA-US209-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:25:37
User entered 'Yes (Y)'	System	26 Apr 2021 17:15:03

US3892032

Folder: SAE USA-US209-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:25:37
User entered 'No (N)'	System	26 Apr 2021 17:15:03

US3892032

Folder: SAE USA-US209-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:25:37
User entered 'No (N)'	System	26 Apr 2021 17:15:03

US3892032

Folder: SAE USA-US209-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:25:37
User entered 'Yes (Y)'	System	26 Apr 2021 17:15:03

US3892032

Folder: SAE USA-US209-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:25:37
User entered 'No (N)'	System	26 Apr 2021 17:15:03

US3892032

Folder: SAE USA-US209-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:25:37
User entered 'No (N)'	System	26 Apr 2021 17:15:03

US3892032

Folder: SAE USA-US209-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:25:37
User entered 'No (N)'	System	26 Apr 2021 17:15:03

US3892032

Folder: SAE USA-US209-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:25:37
User entered 'Michael'	System	26 Apr 2021 17:15:03

US3892032

Folder: SAE USA-US209-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:25:37
User entered 'Adams'	System	26 Apr 2021 17:15:03

US3892032

Folder: SAE USA-US209-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:29

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:25:37
User entered '5251 S Green St'	System	26 Apr 2021 17:15:03

US3892032

Folder: SAE USA-US209-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:29

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:25:37
User entered 'Murray'	System	26 Apr 2021 17:15:03

US3892032

Folder: SAE USA-US209-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:29

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:25:37
User entered 'UT'	System	26 Apr 2021 17:15:03

US3892032

Folder: SAE USA-US209-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:25:37
User entered '84123'	System	26 Apr 2021 17:15:03

US3892032

Folder: SAE USA-US209-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:57
User entered 'US'	(b) (4) System	26 Apr 2021 18:25:42

US3892032

Folder: SAE USA-US209-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:18:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Apr 2021 18:25:42

US3892032

Folder: SAE USA-US209-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:18:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:57
User entered '26/Apr/2021 14:25'	(b) (4) System	26 Apr 2021 18:25:42

US3892032

Folder: SAE USA-US209-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:18:29

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.	Michael Adams (b) (4)	26 Apr 2021 22:39:57
User entered 'I'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:25:42