

US3732262 (Prod: eStudySite - La Mesa - PPDS)

Generated By: KC Joubran

Generated On: 12 Aug 2021 13:22:21

All time stamps listed in this document are displayed in GMT

US3732262

Form: Participant Creation

Data signed: (b) (4) 25 Feb 2021 02:04:48

Generated On: 12 Aug 2021 13:22:21

[Participant ID](#)

US3732262

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

US3732262

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 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	SCRN

US3732262

Folder: Screening

Form: Demographics

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Date of Birth (MMM yyyy)	(b) (6) 1983
Age	37
Age Units	YEARS
Age (Derived)	37
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input 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

US3732262

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Date of Informed Consent (*dd MMM yyyy*) 02 SEP 2020

Month and Year of Informed Consent (derived) SEP 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

US3732262

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3732262

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Were any significant conditions reported?

Yes ☒

No ☐

US3732262

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Condition	ENVIRONMENTAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1996
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 1996
Start Year (derived)	1996
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3732262

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Condition	MYOPIA
Start date (dd MMM yyyy)	UN UNK 1996
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 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

US3732262

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Condition	ASTIGMATISM
Start date (dd MMM yyyy)	UN UNK 1996
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 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

US3732262

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Condition	ROSACEA - FACIAL
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)	_____

US3732262

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Condition	CONSTIPATION
Start date (dd MMM yyyy)	UN UNK 1989
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 1989
Start Year (derived)	1989
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3732262

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Condition	UNCOMPLICATED URINARY TRACT INFECTION
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	JAN 2014
Stop Year (derived)	2014

US3732262

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Condition	IRON DEFICIENCY ANEMIA
Start date (dd MMM yyyy)	UN UNK 1998
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 1999
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	JAN 1999
Stop Year (derived)	1999

US3732262

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Condition	MIGRAINE HEADACHES
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3732262

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Condition	POST-PARTUM DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	JAN 2014
Stop Year (derived)	2014

US3732262

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3732262

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Condition	HUMAN PAPILLOMAVIRUS
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)	_____

US3732262

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Condition	LASIK
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

US3732262

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Condition	MARIJUANA USE - ORAL
Start date (dd MMM yyyy)	UN MAY 2020
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)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3732262

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

US3732262

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Condition	LEFT SPRAINED ANKLE
Start date (dd MMM yyyy)	UN MAR 2020
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)	MAR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3732262

Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Condition	MENSTRUAL CRAMPS
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3732262

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 SEP 2020
Time of assessment (00:00-23:59)	15:09 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 15:09
Height (xxx.x)	161.6 cm
Weight (xxx.x)	81.2 kg
BMI (xxx.x)	31.09377 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3732262

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 SEP 2020

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

US3732262

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Date of assessment (*dd MMM yyyy*) 02 SEP 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

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

Date of last menstruation unknown False

US3732262

Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	02 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3732262

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3732262

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

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

US3732262

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3732262

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

What was the date of randomization? (dd MMM yyyy) 02 SEP 2020

What was the participant's randomization number? 111299

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 ☒

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Height	ND - Not Done
Weight	ND - Not Done

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

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)	02 SEP 2020
Time of assessment (00:00-23:59)	15:09 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 15:09
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)	95 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)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

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)	02 SEP 2020
Time of assessment (00:00-23:59)	16:47 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 16:47
Temperature (xxx.x)	100.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	92 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG

US3732262

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3732262

Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

US3732262

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 02 SEP 2020

What was the treatment time? (00:00-23:59) 16:17 (24 HR)

Treatment Date and Time (derived) 02 SEP 2020 16:17

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

US3732262

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

02 SEP 2020

Collection time (00:00-23:59)

15:59 (24 HR)

Collection date and time (derived)

02 SEP 2020 15:59

US3732262

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Collection date (dd MMM yyyy)			02 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:38	02 SEP 2020 15:38
Nasopharyngeal Swab 2	No		

US3732262

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

100.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 16:53

PC Open Date & Time

02 SEP 2020 16:37

PC Close Date & Time

02 SEP 2020 19:07

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☒

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 22:23

PC Open Date & Time 02 SEP 2020 20:02

PC Close Date & Time 03 SEP 2020 11:59

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 12:03

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

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

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

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

PC Time Stamp	04 SEP 2020 16:03
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

05 SEP 2020 19:16

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 13:24

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 16:37

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 17:22

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 16:55

PC Open Date & Time

02 SEP 2020 16:37

PC Close Date & Time

02 SEP 2020 19:07

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 22:25

PC Open Date & Time

02 SEP 2020 20:02

PC Close Date & Time

03 SEP 2020 11:59

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 12:46

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 16:05

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 19:17

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 13:24

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 16:37

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 13:32

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:22:21

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 16:56
PC Open Date & Time	02 SEP 2020 16:37
PC Close Date & Time	02 SEP 2020 19:07

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

- None ☐
- No interference with activity ☒
- Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐
- Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

- None ☐
- No interference with activity ☐
- Some interference with activity ☒
- Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

- None ☐
- No interference with activity ☐
- Some interference with activity ☒
- Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

- None ☐
- No interference with activity ☐
- Some interference with activity ☒
- Significant; prevents daily
activity ☐

NAUSEA/VOMITING

- None ☒
- No interference with activity or
1-2 episodes/24 hours ☐
- Some interference with activity
or >2 episodes/24 hours ☐
- Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

- None ☒
- No interference with activity ☐
- Some interference with activity
not requiring medical attention ☐
- Prevents daily activity and
requires medical attention ☐

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:22:21

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 22:28
PC Open Date & Time	02 SEP 2020 20:02
PC Close Date & Time	03 SEP 2020 11:59

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

60 of 2563

EAB) (1725)

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:22:21

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 12:47
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

62 of 2563

EAB) (1725)

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:22:21

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 16:08
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

64 of 2563

EAB) (1725)

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:22:21

		Yes <input type="checkbox"/>
PC Time stamp	05 SEP 2020 19:18	
PC Open Date & Time	05 SEP 2020 12:00	
PC Close Date & Time	06 SEP 2020 11:59	

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

66 of 2563

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:22:21

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 13:25
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:22:21

		Yes <input type="checkbox"/>
PC Time stamp	07 SEP 2020 16:38	
PC Open Date & Time	07 SEP 2020 12:00	
PC Close Date & Time	08 SEP 2020 11:59	

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

70 of 2563

EAB) (1725)

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:22:21

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 13:33
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3732262

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732262

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732262

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 02:04:49

Generated On: 12 Aug 2021 13:22:21

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

VISIT WILL BE OMITTED DUE
TO CONVALESCENT PERIOD.

If Contact Not Made, please provide Comments

US3732262

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 02:04:49

Generated On: 12 Aug 2021 13:22:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732262

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 02:04:50

Generated On: 12 Aug 2021 13:22:21

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

SUBJECT WAS IN THE
CONVALESCENT PHASE

If Contact Not Made, please provide Comments

US3732262

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 02:04:49

Generated On: 12 Aug 2021 13:22:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732262

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID VISIT2

US3732262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:21

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	

US3732262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:21

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	

US3732262

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:22:21

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

US3732262

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:21

Was the pregnancy test performed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Date of test (<i>dd MMM yyyy</i>)	<hr/>
Test performed	Urine <input type="checkbox"/>
	Serum <input type="checkbox"/>
Result	Positive <input type="checkbox"/>
	Negative <input type="checkbox"/>
Was FSH sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date	<hr/>
Collection time	<hr/>
Collection date and time (derived)	<hr/>

US3732262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Was study treatment given? Yes ☐
No ☒

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☒
Other ☐

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

What was the study treatment?

What was the treatment date? (dd MMM yyyy)

What was the treatment time? (00:00-23:59)

Treatment Date and Time (derived)

Which arm was used to give treatment? Left Arm ☐
Right Arm ☐

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3732262

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:22:21

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

Collection date (<i>dd MMM yyyy</i>)	_____
Collection time (<i>00:00-23:59</i>)	_____
Collection date and time (derived)	_____

US3732262

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:22:21

Collection date (<i>dd MMM yyyy</i>)			
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1			
Nasopharyngeal Swab 2			

US3732262

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732262

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 02:04:56

Generated On: 12 Aug 2021 13:22:21

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

SUBJECT WAS IN THE
CONVALESCENT PHASE

If Contact Not Made, please provide Comments

US3732262

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 02:04:56

Generated On: 12 Aug 2021 13:22:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732262

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 02:04:56

Generated On: 12 Aug 2021 13:22:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732262

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 02:04:56

Generated On: 12 Aug 2021 13:22:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732262

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732262

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 02:04:56

Generated On: 12 Aug 2021 13:22:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732262

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 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	VISIT3

US3732262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 NOV 2020
Time of assessment (00:00-23:59)	14:38 (24 HR)
Vital Signs Date and Time (derived)	04 NOV 2020 14:38
Temperature (xxx.x)	99.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3732262

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 NOV 2020

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

US3732262

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

04 NOV 2020

Collection time (00:00-23:59)

14:52 (24 HR)

Collection date and time (derived)

04 NOV 2020 14:52

US3732262

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 NOV 2020 18:00:22

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3732262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 NOV 2020 02:45:52

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3732262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 NOV 2020 00:01:46

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2020 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 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 NOV 2020 00:04:11
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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	04 DEC 2020 01:15:43
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 15:19:03

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 DEC 2020 00:52:25

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 DEC 2020 05:57:49

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	01 JAN 2021 16:53:36
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 JAN 2021 08:10:02
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	15 JAN 2021 16:50:19
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 JAN 2021 00:38:19

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 JAN 2021 02:39:58
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 FEB 2021 18:18:24

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 FEB 2021 18:39:45

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 08:57:32

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	26 FEB 2021 08:03:39
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	07 MAR 2021 12:00:46
Patient Cloud Open Date & Time	05 MAR 2021 00:01
Patient Cloud Close Date & Time	09 MAR 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 MAR 2021 14:00:10
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	19 MAR 2021 01:52:17
Patient Cloud Open Date & Time	19 MAR 2021 00:01
Patient Cloud Close Date & Time	23 MAR 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 MAR 2021 01:03:31

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 12:00:26

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 19:39:22

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 APR 2021 02:00:54

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

23 APR 2021 15:29:14

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 12:29:01

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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="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"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 <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"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 <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"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 ☐

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 <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°F/38°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"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 ☐

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 <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"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 <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"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 ☐

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 ☐

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

Patient Cloud Open Date & Time	15 OCT 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	19 OCT 2021 23:59
---	-------------------

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 ☐

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 <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"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 ☐

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 <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"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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="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"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 ☐

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 <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"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission	
Patient Cloud Open Date & Time	10 DEC 2021 00:01
Patient Cloud Close Date & Time	14 DEC 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 ☐

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 <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"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 ☐

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 <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"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 ☐

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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="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"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 ☐

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 ☐

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 ☐

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 ☐

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 <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"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 ☐

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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="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"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 <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"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 <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"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 642

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

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

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

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

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

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

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 ☐

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 <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"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 ☐

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 ☐

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 ☐

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 ☐

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 <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"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission	
Patient Cloud Open Date & Time	15 JUL 2022 00:01
Patient Cloud Close Date & Time	19 JUL 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 <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"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 <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"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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="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"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 <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"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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="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"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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="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°F/38°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"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 ☐

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 ☐

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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 ☐

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Date and time of submission	
Patient Cloud Open Date & Time	21 OCT 2022 00:01
Patient Cloud Close Date & Time	25 OCT 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3732262

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 12 Aug 2021 13:22:21

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 08:29:02

US3732262

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732262

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 02:04:57

Generated On: 12 Aug 2021 13:22:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732262

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 02:04:49

Generated On: 12 Aug 2021 13:22:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732262

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 02:04:49

Generated On: 12 Aug 2021 13:22:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732262

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 02:04:49

Generated On: 12 Aug 2021 13:22:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732262

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 02:04:49

Generated On: 12 Aug 2021 13:22:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732262

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 21:26:16

Generated On: 12 Aug 2021 13:22:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732262

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732262

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 21:26:16

Generated On: 12 Aug 2021 13:22:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3732262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 21:26:16

Generated On: 12 Aug 2021 13:22:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	30 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	13:41 (24 HR)
Vital Signs Date and Time (derived)	30 MAR 2021 13:41
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>)	82 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	19 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	97 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3732262

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 21:26:16

Generated On: 12 Aug 2021 13:22:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 MAR 2021

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

US3732262

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 21:26:16

Generated On: 12 Aug 2021 13:22:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 MAR 2021
Collection time (00:00-23:59)	13:53 (24 HR)
Collection date and time (derived)	30 MAR 2021 13:53

US3732262

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 21:26:16

Generated On: 12 Aug 2021 13:22:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732262

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 21:19:55

Generated On: 12 Aug 2021 13:22:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732262

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 21:19:55

Generated On: 12 Aug 2021 13:22:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732262

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

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

US3732262

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:21

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 28 Apr 2021 22:22:46

Generated On: 12 Aug 2021 13:22:21

Date of Contact	08 SEP 2020
Time of Contact	14:01
Date and Time of Contact (derived)	08 SEP 2020 14:01
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input checked="" type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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"/>

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	100.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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)

304 of 2563

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

305 of 2563

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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"/>

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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)

308 of 2563

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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"/>

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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)

312 of 2563

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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"/>

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	99.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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)

316 of 2563

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

317 of 2563

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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"/>

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	99.1 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)

320 of 2563

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

321 of 2563

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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"/>

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

324 of 2563

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

325 of 2563

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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"/>

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

328 of 2563

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

329 of 2563

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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"/>

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.7 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)

332 of 2563

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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"/>

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	99.1 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)

336 of 2563

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

337 of 2563

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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 type="checkbox"/>
Day 14	<input checked="" 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"/>

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

340 of 2563

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

341 of 2563

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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 type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input checked="" 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"/>

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

	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	21 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
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 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)

344 of 2563

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

345 of 2563

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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 type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input checked="" 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"/>

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

	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	22 SEP 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 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)

348 of 2563

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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 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 checked="" 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"/>

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

	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	23 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.7 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)

352 of 2563

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

353 of 2563

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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 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 checked="" 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"/>

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	99.1 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)

356 of 2563

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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 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 checked="" type="checkbox"/>

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

	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	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 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)

360 of 2563

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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 type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input checked="" 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"/>

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

	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	20 SEP 2020	
Assessment Not Done	True	
O2 Saturation	<hr/>	
O2 Saturation Units	<hr/>	
Temperature	<hr/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

364 of 2563

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

	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)

365 of 2563

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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"/>

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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"/>

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

368 of 2563

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

369 of 2563

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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"/>

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

372 of 2563

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

373 of 2563

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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"/>

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

376 of 2563

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

377 of 2563

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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"/>

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

380 of 2563

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 25 Feb 2021 02:04:48

Generated On: 12 Aug 2021 13:22:21

Date of Visit	10 SEP 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 checked="" type="radio"/> No <input type="radio"/>
Date of Test	10 SEP 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)	1

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ $\leq 93\%$ on room air at sea level? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date _____

PRODUCTION RELEASE (v12.003

EAB) (1725)

384 of 2563

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

If Yes to either Did subject require any of the following:

Ventilator Support:

High-Flow Oxygen?

Yes ☐

No ☒

Start Date

End Date

Non-Invasive Ventilation?

Yes ☐

No ☐

Start Date

End Date

Mechanical Ventilation?

Yes ☐

No ☐

Start Date

End Date

ECMO?

Yes ☐

No ☐

Start Date

End Date

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors

Yes ☐

No ☒

Start Date

End Date

Acute Renal Dysfunction?

Yes ☐

No ☒

Start Date

PRODUCTION RELEASE (v12.003

EAB) (1725)

385 of 2563

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

Hepatic Dysfunction? Yes ☐
No ☒

Start Date

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐
No ☒

Start Date

End Date

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 25 Feb 2021 02:04:48

Generated On: 12 Aug 2021 13:22:21

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3732262

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 25 Feb 2021 02:04:49

Generated On: 12 Aug 2021 13:22:21

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	12 SEP 2020
Day 5	Yes	14 SEP 2020
Day 7	Yes	16 SEP 2020
Day 9	Yes	18 SEP 2020
Day 14	Yes	23 SEP 2020
Day 21	Yes	30 SEP 2020
Day 28	Yes	07 OCT 2020

US3732262

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 02:04:49

Generated On: 12 Aug 2021 13:22:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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	SICKD1

US3732262

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Feb 2021 02:04:49

Generated On: 12 Aug 2021 13:22:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	12:15 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 12:15
Height (xxx.x)	161.6 cm
Weight (xxx.x)	81.0 kg
Temperature (xxx.x)	100.0 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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3732262

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 02:04:49

Generated On: 12 Aug 2021 13:22:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

US3732262

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 25 Feb 2021 02:04:49

Generated On: 12 Aug 2021 13:22:21

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

10 SEP 2020

US3732262

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 02:04:48

Generated On: 12 Aug 2021 13:22:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 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	SICKD28

US3732262

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Feb 2021 02:04:48

Generated On: 12 Aug 2021 13:22:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 OCT 2020
Time of assessment (00:00-23:59)	14:05 (24 HR)
Vital Signs Date and Time (derived)	07 OCT 2020 14:05
Height (xxx.x)	162.3 cm
Weight (xxx.x)	080.3 kg
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	92 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3732262

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 02:04:48

Generated On: 12 Aug 2021 13:22:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 OCT 2020

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

US3732262

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 25 Feb 2021 02:04:48

Generated On: 12 Aug 2021 13:22:21

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

07 OCT 2020

US3732262

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

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 02:04:49

Generated On: 12 Aug 2021 13:22:21

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

Visit date (dd MMM yyyy)	23 FEB 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
------------	---------------

US3732262

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

Form: Unblinding

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

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

US3732262

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

Height	
Weight	
BMI (xxx.x)	

US3732262

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 FEB 2021
Time of assessment (00:00-23:59)	14:41 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 14:41
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3732262

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 FEB 2021
Time of assessment (00:00-23:59)	15:49 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 15:49
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3732262

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

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 FEB 2021

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

US3732262

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

Form: Pregnancy Test

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	26 FEB 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3732262

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

Form: Exposure

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 26 FEB 2021

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

Treatment Date and Time (derived) 26 FEB 2021 15:14

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

US3732262

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Feb 2021 02:04:49

Generated On: 12 Aug 2021 13:22:21

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 FEB 2021

Collection time (00:00-23:59)

14:11 (24 HR)

Collection date and time (derived)

23 FEB 2021 14:11

US3732262

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 25 Feb 2021 02:04:49

Generated On: 12 Aug 2021 13:22:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 FEB 2021
Collection time (00:00 - 23:59)	14:14
Collection Date and Time (derived)	23 FEB 2021 14:14

US3732262

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

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732262

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 21:26:16

Generated On: 12 Aug 2021 13:22:21

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

US3732262

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 21:26:16

Generated On: 12 Aug 2021 13:22:21

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

US3732262

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 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

US3732262

Folder: OL-D29 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 MAR 2021
Time of assessment (00:00-23:59)	13:41 (24 HR)
Vital Signs Date and Time (derived)	30 MAR 2021 13:41
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	19 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	97 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3732262

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 MAR 2021

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

US3732262

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

30 MAR 2021

Collection time (00:00-23:59)

13:52 (24 HR)

Collection date and time (derived)

30 MAR 2021 13:52

US3732262

Folder: Unscheduled 26 Feb 2021

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 09 Apr 2021 21:26:16

Generated On: 12 Aug 2021 13:22:21

Visit Date	26 FEB 2021
Please check all assessments that apply for this visit	
Physical Exam	False
Vital Signs	True
Immunogenicity Assessment	False
Pregnancy Test	False

US3732262

Folder: Unscheduled 26 Feb 2021

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 21:26:16

Generated On: 12 Aug 2021 13:22:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	26 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	14:47 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 14:47
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>)	76 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3732262

Folder: Unscheduled 30 Mar 2021

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 09 Apr 2021 21:26:16

Generated On: 12 Aug 2021 13:22:21

Visit Date	30 MAR 2021
Please check all assessments that apply for this visit	
Physical Exam	False
Vital Signs	True
Immunogenicity Assessment	False
Pregnancy Test	False

US3732262

Folder: Unscheduled 30 Mar 2021

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 21:26:16

Generated On: 12 Aug 2021 13:22:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	30 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	13:49 (24 HR)
Vital Signs Date and Time (derived)	30 MAR 2021 13:49
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>)	85 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	19 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	93 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3732262

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 25 Feb 2021 02:04:48

Generated On: 12 Aug 2021 13:22:21

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 25 Feb 2021 02:04:48

Generated On: 12 Aug 2021 13:22:21

AEID	USA-US102-2020-MRNA-1273-P30 1000001
Adverse event	SYMPTOMATIC COVID-19
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 checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	06 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)	19 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

419 of 2563

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 25 Feb 2021 02:04:48

Generated On: 12 Aug 2021 13:22:21

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input 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 checked="" type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 25 Feb 2021 02:04:48

Generated On: 12 Aug 2021 13:22:21

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

Yes ☒

No ☐

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

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 25 Feb 2021 02:04:48

Generated On: 12 Aug 2021 13:22:21

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

422 of 2563

EAB) (1725)

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 25 Feb 2021 02:04:48

Generated On: 12 Aug 2021 13:22:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JUN 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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 25 Feb 2021 02:04:48

Generated On: 12 Aug 2021 13:22:21

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication MIGRAINE HEADACHES

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

424 of 2563

EAB) (1725)

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 25 Feb 2021 02:04:48

Generated On: 12 Aug 2021 13:22:21

	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 2017	
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"/>

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 25 Feb 2021 02:04:48

Generated On: 12 Aug 2021 13:22:21

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication E-DIARY PAIN - HEADACHE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

426 of 2563

EAB) (1725)

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 25 Feb 2021 02:04:48

Generated On: 12 Aug 2021 13:22:21

	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)		04 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) 04 SEP 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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"/>

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 25 Feb 2021 02:04:48

Generated On: 12 Aug 2021 13:22:21

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication SYMPTOMATIC COVID-19

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

428 of 2563

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 25 Feb 2021 02:04:48

Generated On: 12 Aug 2021 13:22:21

	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 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) 19 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"/>

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 25 Feb 2021 02:04:48

Generated On: 12 Aug 2021 13:22:21

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication MENSTRUAL CRAMPS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

430 of 2563

EAB) (1725)

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 25 Feb 2021 02:04:48

Generated On: 12 Aug 2021 13:22:21

	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 2014	
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"/>

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 25 Feb 2021 02:04:48

Generated On: 12 Aug 2021 13:22:21

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication LEFT SPRAINED ANKLE

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

432 of 2563

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 25 Feb 2021 02:04:48

Generated On: 12 Aug 2021 13:22:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN MAR 2020	
Start date completely unknown	False	
Ongoing?	Yes	<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"/>

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 25 Feb 2021 02:04:48

Generated On: 12 Aug 2021 13:22:21

Name of Medication FLU VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA

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 ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

434 of 2563

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 25 Feb 2021 02:04:48

Generated On: 12 Aug 2021 13:22:21

	Intramuscular	<input checked="" 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 type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		16 OCT 2020
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"/>

US3732262

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3732262

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:22:21

Visit	Screening	<input type="checkbox"/>
	Visit 1 Day 1	<input type="checkbox"/>
	Visit 2 Day 29	<input type="checkbox"/>
	Visit 3 Day 57	<input type="checkbox"/>
	Visit 4 Day 209	<input type="checkbox"/>
	Visit 5 Day 394	<input type="checkbox"/>
	Visit 6 Day 759	<input type="checkbox"/>

Case Report Form

Visit Date	
Demographics	
Enrollment	
Inclusion/Exclusion Criteria Summary	
Inclusion/Exclusion Criteria	
Medical History Summary	
Medical History	
Vital Signs	
Vital Signs - Dosing	
Physical Examination	
Central Laboratory - Nasopharyngeal Swab	
Childbearing Potential	
Pregnancy Test	
Randomization	
Exposure	
Immunogenicity Assessment	
Saliva Collection	
COVID Diagnostic Test	
Symptom Log	
Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection	
COVID-19 Severity Assessment	
COVID-19 Contact	
Risk of Exposure	
Safety Call	
Dosing Discontinuation	
End of Study / Study Discontinuation	

US3732262

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:22:21

All	
Date of missed or out of window visit or assessment	
Category	
Inclusion criteria not met/Exclusion criteria met	
Study Treatment not given	
Missed Visit	
Missed Assessment	
Visit performed out of window	
Assessment performed out of window	
Scheduled clinical visit performed as home visit	
Other	
Other, specify	
Description of Relationship to COVID-19	
Clinical site closed	
Travel restrictions	
Quarantine due to COVID-19	
Possible exposure to COVID-19	
Exposure to COVID-19	
Presumption / confirmed COVID-19	
Symptoms of COVID-19	
Sponsor hold due to COVID-19	
Participant decision	

US3732262

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 09 Apr 2021 21:25:45

Generated On: 12 Aug 2021 13:22:21

Date of dosing discontinuation (dd MMM yyyy) 06 SEP 2020

Primary reason for dosing discontinuation

AE (specify)	<input checked="" type="radio"/>
SAE (specify)	<input type="radio"/>
Death	<input type="radio"/>
Lost To Follow-up	<input type="radio"/>
Physician decision (specify)	<input type="radio"/>
Pregnancy	<input type="radio"/>
Protocol deviation (specify)	<input type="radio"/>
Study Terminated By Sponsor	<input type="radio"/>
Withdrawal of consent by participant (specify)	<input type="radio"/>
Due to SARS-COV-2	<input type="radio"/>
Other	<input type="radio"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify SYMPTOMATIC COVID-19 AE #1

US3732262

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:22:21

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 ☐

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 25 Feb 2021 02:04:49

Generated On: 12 Aug 2021 13:22:21

SAEID	USA-US102-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 25 Feb 2021 02:04:49

Generated On: 12 Aug 2021 13:22:21

SAEID	USA-US102-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	10/SEP/2020 12:43
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 25 Feb 2021 02:04:49

Generated On: 12 Aug 2021 13:22:21

SAEID	USA-US102-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	23/SEP/2020 13:55
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

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 25 Feb 2021 02:04:49

Generated On: 12 Aug 2021 13:22:21

SAEID	USA-US102-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	08/OCT/2020 13:57
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

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 25 Feb 2021 02:04:49

Generated On: 12 Aug 2021 13:22:21

SAEID	USA-US102-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	15/OCT/2020 10:15
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

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 25 Feb 2021 02:04:49

Generated On: 12 Aug 2021 13:22:21

SAEID	USA-US102-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	06/NOV/2020 19:14
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3732262 (Prod: eStudySite - La Mesa - PPDS)

US3732262

Form: Participant Creation

Generated On: 12 Aug 2021 13:22:21

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:40:12
User entered 'US3732262'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 22:09:22

US3732262

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:22:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:40:31
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:22:57

US3732262

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:40:31
User entered '02 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 22:09:23

US3732262

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:40:31
User entered 'Clinic (Clinic)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:22:57

US3732262

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:22:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered 'SCRN'	System	04 Sep 2020 18:22:57

US3732262

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:22:21

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:43:47
User entered (b) (6) 1983'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 22:09:24

US3732262

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:22:21

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:43:47
User entered '37'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:23:23

US3732262

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:22:21

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered 'YEARS'	System	04 Sep 2020 18:23:23

US3732262

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:22:21

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered '37'	System	02 Sep 2020 23:18:46

US3732262

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:22:21

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:43:47
User entered 'Female (F)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:23:23

US3732262

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:22:21

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:43:47
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:23:23

US3732262

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:22:21

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:43:47
User entered 'l'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:23:23

US3732262

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:22:21

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:43:47
User entered '0'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:23:23

US3732262

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:22:21

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:43:47
User entered '0'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:23:23

US3732262

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:22:21

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:43:47
User entered '0'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:23:23

US3732262

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:22:21

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:43:47
User entered '0'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:23:23

US3732262

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:22:21

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:43:47
User entered '0'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:23:23

US3732262

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:22:21

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:43:47
User entered empty.	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:23:23

US3732262

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:22:21

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:43:47
User entered '0'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:23:23

US3732262

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:22:21

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:43:47
User entered '0'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:23:23

US3732262

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:22:21

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:46:55
User entered '02 Sep 2020'	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 23:18:46

US3732262

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered 'Sep 2020'	System	02 Sep 2020 23:18:46

US3732262

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered '2020'	System	02 Sep 2020 23:18:46

US3732262

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:22:21

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:46:55
User entered 'Amendment 3 (3)'	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 23:18:46

US3732262

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:46:55
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 23:18:46

US3732262

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:22:21

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:46:55
User entered empty.	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 23:18:46

US3732262

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:22:21

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:46:55
User entered empty.	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 23:18:46

US3732262

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:22:21

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:46:55
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 23:18:46

US3732262

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:22:21

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:46:55
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 22:09:23

US3732262

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:22:21

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered 'I'	System	02 Sep 2020 23:18:51

US3732262

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:47:03
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 23:18:51

US3732262

Folder: Screening

Form: Medical History Summary

Generated On: 12 Aug 2021 13:22:21

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:47:10
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:23:28

US3732262

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:22:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Hypersensitivity, LLT: Environmental allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:25:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:25:41
Data point term sent to Coder	System	04 Sep 2020 18:24:26
User entered 'environmental allergies'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:23:47

US3732262

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered 'un UNK 1996'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:23:47

US3732262

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:22:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered '0'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:23:47

US3732262

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:22:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:23:47

US3732262

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:22:21

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered empty.	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:23:47

US3732262

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:22:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered '0'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:23:47

US3732262

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:22:21

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered 'Jan 1996'	System	04 Sep 2020 18:23:47

US3732262

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered '1996'	System	04 Sep 2020 18:23:47

US3732262

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered empty.	System	04 Sep 2020 18:23:47

US3732262

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered empty.	System	04 Sep 2020 18:23:47

US3732262

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:22:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Myopia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:25:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:25:43
Data point term sent to Coder	System	04 Sep 2020 18:24:27
User entered 'myopia'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:24:01

US3732262

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered 'un UNK 1996'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:24:01

US3732262

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:22:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered '0'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:24:01

US3732262

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:22:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:24:01

US3732262

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:22:21

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered 'un UNK 2010'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:24:01

US3732262

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:22:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered '0'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:24:01

US3732262

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered 'Jan 1996'	System	04 Sep 2020 18:24:01

US3732262

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered '1996'	System	04 Sep 2020 18:24:01

US3732262

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered 'Jan 2010'	System	04 Sep 2020 18:24:01

US3732262

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered '2010'	System	04 Sep 2020 18:24:01

US3732262

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:22:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Astigmatism, LLT: Astigmatism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:25:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:25:43
Data point term sent to Coder	System	04 Sep 2020 18:24:26
User entered 'astigmatism'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:24:17

US3732262

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered 'un UNK 1996'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:24:17

US3732262

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:22:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered '0'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:24:17

US3732262

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:22:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:24:17

US3732262

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:22:21

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered 'un UNK 2010'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:24:17

US3732262

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:22:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered '0'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:24:17

US3732262

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered 'Jan 1996'	System	04 Sep 2020 18:24:17

US3732262

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered '1996'	System	04 Sep 2020 18:24:17

US3732262

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered 'Jan 2010'	System	04 Sep 2020 18:24:17

US3732262

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered '2010'	System	04 Sep 2020 18:24:17

US3732262

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:22:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Rosaceas, PT: Rosacea, LLT: Rosacea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 09:15:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 09:15:54
Data point term sent to Coder	System	04 Sep 2020 18:25:30
User entered 'rosacea - facial'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:24:33

US3732262

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered 'un UNK 2013'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:24:33

US3732262

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:22:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered '0'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:24:33

US3732262

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:22:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:24:33

US3732262

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:22:21

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered empty.	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:24:33

US3732262

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:22:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered '0'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:24:33

US3732262

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:22:21

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered 'Jan 2013'	System	04 Sep 2020 18:24:33

US3732262

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:22:21

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered '2013'	System	04 Sep 2020 18:24:33

US3732262

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered empty.	System	04 Sep 2020 18:24:33

US3732262

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered empty.	System	04 Sep 2020 18:24:33

US3732262

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:22:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User coded data point as SOC: Gastrointestinal disorders, HLT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:26:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:26:46
Data point term sent to Coder	System	04 Sep 2020 18:25:28
User entered 'constipation'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:24:44

US3732262

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered 'un UNK 1989'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:24:44

US3732262

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:22:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered '0'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:24:44

US3732262

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:22:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:24:44

US3732262

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:22:21

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered empty.	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:24:44

US3732262

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:22:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered '0'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:24:44

US3732262

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered 'Jan 1989'	System	04 Sep 2020 18:24:44

US3732262

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered '1989'	System	04 Sep 2020 18:24:44

US3732262

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered empty.	System	04 Sep 2020 18:24:44

US3732262

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered empty.	System	04 Sep 2020 18:24:44

US3732262

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:22:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:26:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:26:46
Data point term sent to Coder	System	04 Sep 2020 18:25:30
User entered 'uncomplicated urinary tract infection'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:25:04

US3732262

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered 'un UNK 2014'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:25:04

US3732262

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:22:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered '0'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:25:04

US3732262

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:22:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:25:04

US3732262

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:22:21

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered 'un UNK 2014'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:25:04

US3732262

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:22:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered '0'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:25:04

US3732262

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered 'Jan 2014'	System	04 Sep 2020 18:25:04

US3732262

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered '2014'	System	04 Sep 2020 18:25:04

US3732262

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered 'Jan 2014'	System	04 Sep 2020 18:25:04

US3732262

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered '2014'	System	04 Sep 2020 18:25:04

US3732262

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:22:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemia deficiencies, PT: Iron deficiency anaemia, LLT: Iron deficiency anemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:26:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:26:46
Data point term sent to Coder	System	04 Sep 2020 18:25:30
User entered 'iron deficiency anemia'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:25:23

US3732262

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered 'un UNK 1998'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:25:23

US3732262

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:22:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered '0'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:25:23

US3732262

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:22:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:25:23

US3732262

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:22:21

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered 'un UNK 1999'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:25:23

US3732262

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:22:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered '0'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:25:23

US3732262

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:22:21

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered 'Jan 1998'	System	04 Sep 2020 18:25:23

US3732262

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered '1998'	System	04 Sep 2020 18:25:23

US3732262

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered 'Jan 1999'	System	04 Sep 2020 18:25:23

US3732262

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered '1999'	System	04 Sep 2020 18:25:23

US3732262

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:22:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:27:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:27:47
Data point term sent to Coder	System	04 Sep 2020 18:26:32
User entered 'migraine headaches'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:25:34

US3732262

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered 'un UNK 2017'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:25:34

US3732262

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:22:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered '0'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:25:34

US3732262

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:22:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:25:34

US3732262

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered empty.	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:25:34

US3732262

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:22:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered '0'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:25:34

US3732262

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered 'Jan 2017'	System	04 Sep 2020 18:25:34

US3732262

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered '2017'	System	04 Sep 2020 18:25:34

US3732262

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered empty.	System	04 Sep 2020 18:25:34

US3732262

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered empty.	System	04 Sep 2020 18:25:34

US3732262

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:22:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Perinatal depression, LLT: Postpartum depression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:28:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:28:39
Data point term sent to Coder	System	04 Sep 2020 18:27:43
User entered 'post-partum depression'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:26:37

US3732262

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered 'un UNK 2014'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:26:37

US3732262

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:22:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered '0'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:26:37

US3732262

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:22:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:26:37

US3732262

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:22:21

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered 'un UNK 2014'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:26:37

US3732262

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:22:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered '0'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:26:37

US3732262

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered 'Jan 2014'	System	04 Sep 2020 18:26:37

US3732262

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered '2014'	System	04 Sep 2020 18:26:37

US3732262

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered 'Jan 2014'	System	04 Sep 2020 18:26:37

US3732262

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered '2014'	System	04 Sep 2020 18:26:37

US3732262

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:22:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:28:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:28:39
Data point term sent to Coder	System	04 Sep 2020 18:27:43
User entered 'anxiety'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:26:56

US3732262

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered 'un UNK 2014'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:26:56

US3732262

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:22:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered '0'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:26:56

US3732262

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:22:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:26:56

US3732262

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered empty.	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:26:56

US3732262

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:22:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered '0'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:26:56

US3732262

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered 'Jan 2014'	System	04 Sep 2020 18:26:56

US3732262

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered '2014'	System	04 Sep 2020 18:26:56

US3732262

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered empty.	System	04 Sep 2020 18:26:56

US3732262

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered empty.	System	04 Sep 2020 18:26:56

US3732262

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:22:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Papilloma viral infections, PT: Papilloma viral infection, LLT: Human papilloma virus infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:28:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:28:39
Data point term sent to Coder	System	04 Sep 2020 18:27:44
User entered 'human papillomavirus'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:27:25

US3732262

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered 'un UNK 2019'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:27:25

US3732262

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:22:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered '0'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:27:25

US3732262

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:22:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:27:25

US3732262

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered empty.	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:27:25

US3732262

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:22:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered '0'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:27:25

US3732262

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:22:21

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered 'Jan 2019'	System	04 Sep 2020 18:27:25

US3732262

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered '2019'	System	04 Sep 2020 18:27:25

US3732262

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered empty.	System	04 Sep 2020 18:27:25

US3732262

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered empty.	System	04 Sep 2020 18:27:25

US3732262

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:22:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Corneal and scleral therapeutic procedures, PT: Keratomileusis, LLT: LASIK eye surgery - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:28:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:28:39
Data point term sent to Coder	System	04 Sep 2020 18:27:44
User entered 'lasik'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:27:37

US3732262

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered 'un UNK 2010'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:27:37

US3732262

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:22:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered '0'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:27:37

US3732262

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:22:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:27:37

US3732262

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:22:21

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered 'un UNK 2010'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:27:37

US3732262

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:22:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered '0'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:27:37

US3732262

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered 'Jan 2010'	System	04 Sep 2020 18:27:37

US3732262

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered '2010'	System	04 Sep 2020 18:27:37

US3732262

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered 'Jan 2010'	System	04 Sep 2020 18:27:37

US3732262

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered '2010'	System	04 Sep 2020 18:27:37

US3732262

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:22:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User coded data point as SOC: Social circumstances, HLT: Lifestyle issues, HLT: Social issues NEC, PT: Substance use, LLT: Marijuana use - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 17:53:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 17:53:40
Data point term sent to Coder	System	04 Sep 2020 18:28:45
User entered 'marijuana use - oral'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:28:02

US3732262

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered 'un May 2020'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:28:02

US3732262

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:22:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered '0'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:28:02

US3732262

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:22:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:28:02

US3732262

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:22:21

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered empty.	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:28:02

US3732262

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:22:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered '0'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:28:02

US3732262

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered 'May 2020'	System	04 Sep 2020 18:28:02

US3732262

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered '2020'	System	04 Sep 2020 18:28:02

US3732262

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered empty.	System	04 Sep 2020 18:28:02

US3732262

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered empty.	System	04 Sep 2020 18:28:02

US3732262

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:22:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
User closed query 'Per Medical HX Log; Please add "Left Sprained Ankle UK/MAR/2020-?"' (Site from CRA).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:36:50
Query 'Per Medical HX Log; Please add "Left Sprained Ankle UK/MAR/2020-?"' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 19:19:11
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:50:18
User opened query 'Per Medical HX Log; Please add "Left Sprained Ankle UK/MAR/2020-?"' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 22:48:35
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 22:13:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 22:13:24
Data point term sent to Coder	System	13 Oct 2020 22:12:36
User entered 'HYPERTENSION'	(b) (4), (b) (6)	13 Oct 2020 22:12:13

US3732262

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered 'UN UNK 2014'	(b) (4), (b) (6)	13 Oct 2020 22:12:13

US3732262

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:22:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 22:12:13

US3732262

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:22:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 22:12:13

US3732262

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:22:21

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 22:12:13

US3732262

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:22:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:50:18
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 22:12:13

US3732262

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:22:21

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered 'Jan 2014'	System	13 Oct 2020 22:12:13

US3732262

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered '2014'	System	13 Oct 2020 22:12:13

US3732262

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered empty.	System	13 Oct 2020 22:12:13

US3732262

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered empty.	System	13 Oct 2020 22:12:13

US3732262

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:22:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:38:17
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Ligament sprain, LLT: Sprained ankle - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 06:12:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 06:12:32
Data point term sent to Coder	System	05 Nov 2020 19:20:30
User entered 'Left Sprained Ankle'	(b) (4), (b) (6)	05 Nov 2020 19:19:35

US3732262

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:38:17
User entered 'un Mar 2020'	(b) (4), (b) (6)	05 Nov 2020 19:19:35

US3732262

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:22:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:38:17
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 19:19:35

US3732262

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:22:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:38:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 19:19:35

US3732262

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:22:21

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:38:17
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:19:35

US3732262

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:22:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:38:17
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 19:19:35

US3732262

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered 'Mar 2020'	System	05 Nov 2020 19:19:35

US3732262

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered '2020'	System	05 Nov 2020 19:19:35

US3732262

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered empty.	System	05 Nov 2020 19:19:35

US3732262

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered empty.	System	05 Nov 2020 19:19:35

US3732262

Folder: Screening

Form: Medical History (16)

Generated On: 12 Aug 2021 13:22:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:38:17
User coded data point as SOC: Reproductive system and breast disorders, HLG: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation and uterine bleeding NEC, PT: Dysmenorrhoea, LLT: Menstrual cramps - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 19:21:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 19:21:23
Data point term sent to Coder	System	05 Nov 2020 19:20:32
User entered 'Menstrual Cramps'	(b) (4), (b) (6)	05 Nov 2020 19:20:29

US3732262

Folder: Screening

Form: Medical History (16)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:38:17
User entered 'un UNK 2014'	(b) (4), (b) (6)	05 Nov 2020 19:20:29

US3732262

Folder: Screening

Form: Medical History (16)

Generated On: 12 Aug 2021 13:22:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:38:17
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 19:20:29

US3732262

Folder: Screening

Form: Medical History (16)

Generated On: 12 Aug 2021 13:22:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:38:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 19:20:29

US3732262

Folder: Screening

Form: Medical History (16)

Generated On: 12 Aug 2021 13:22:21

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:38:17
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:20:29

US3732262

Folder: Screening

Form: Medical History (16)

Generated On: 12 Aug 2021 13:22:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:38:17
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 19:20:29

US3732262

Folder: Screening

Form: Medical History (16)

Generated On: 12 Aug 2021 13:22:21

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered 'Jan 2014'	System	05 Nov 2020 19:20:29

US3732262

Folder: Screening

Form: Medical History (16)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered '2014'	System	05 Nov 2020 19:20:29

US3732262

Folder: Screening

Form: Medical History (16)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered empty.	System	05 Nov 2020 19:20:29

US3732262

Folder: Screening

Form: Medical History (16)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered empty.	System	05 Nov 2020 19:20:29

US3732262

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:51:10
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:30:06

US3732262

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:51:10
User entered '02 Sep 2020'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:30:06

US3732262

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:51:10
User entered '15:09'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:30:06

US3732262

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered '02 Sep 2020 15:09'	System	04 Sep 2020 18:30:06

US3732262

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:51:10
User entered '161.6' cm	Lauren Arnett (b) (4)	04 Sep 2020 18:30:06
DataPoint set to visible.	(b) (4) System	02 Sep 2020 23:18:51

US3732262

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:51:10
User entered '81.2' kg	Lauren Arnett (b) (4)	04 Sep 2020 18:30:06
DataPoint set to visible.	(b) (4) System	02 Sep 2020 23:18:51

US3732262

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered '31.09377'	System	04 Sep 2020 18:30:06
DataPoint set to visible.	System	02 Sep 2020 23:18:51

US3732262

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered 'kg/m2'	System	04 Sep 2020 18:30:06
DataPoint set to visible.	System	02 Sep 2020 23:18:51

US3732262

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:51:10
User entered missing code ND - Not Done.	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:30:06

US3732262

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:51:10
User entered empty.	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:30:06

US3732262

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:51:10
User entered empty.	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:30:06

US3732262

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:51:10
User entered missing code ND - Not Done.	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:30:06

US3732262

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered 'bpm'	System	04 Sep 2020 18:30:06

US3732262

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:51:10
User entered missing code ND - Not Done.	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:30:06

US3732262

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered 'breaths/min'	System	04 Sep 2020 18:30:06

US3732262

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:51:10
User entered missing code ND - Not Done.	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:30:06

US3732262

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered 'mmHg'	System	04 Sep 2020 18:30:06

US3732262

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:51:10
User entered missing code ND - Not Done.	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:30:06

US3732262

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered 'mmHg'	System	04 Sep 2020 18:30:06

US3732262

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50

US3732262

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50

US3732262

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:22:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:51:19
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:30:13

US3732262

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:22:21

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:51:19
User entered '02 Sep 2020'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:30:13

US3732262

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:22:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:51:29
User entered '02 Sep 2020'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:30:29

US3732262

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:22:21

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:51:29
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:30:29

US3732262

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:22:21

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:51:29
User entered empty.	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:30:29

US3732262

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:22:21

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:51:29
User entered empty.	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:30:29

US3732262

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:51:29
User entered empty.	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:30:29

US3732262

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:22:21

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:51:29
User entered '0'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:30:29

US3732262

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:51:29
User entered empty.	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:30:29

US3732262

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:22:21

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:51:29
User entered '0'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:30:29

US3732262

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:21

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:51:52
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:30:50

US3732262

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:21

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:51:52
User entered '02 Sep 2020'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:30:50

US3732262

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:21

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:51:52
User entered 'Urine (URINE)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:30:50

US3732262

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:21

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:51:52
User entered 'Negative (NEGATIVE)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:30:50

US3732262

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:21

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:51:52
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:30:50

US3732262

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:21

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:51:52
User entered empty.	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:30:50

US3732262

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:21

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:51:52
User entered empty.	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:30:50

US3732262

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User entered empty.	System	04 Sep 2020 18:30:50

US3732262

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:22:21

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:52:28
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:31:20

US3732262

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:22:21

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:52:28
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:31:20

US3732262

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:22:21

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:52:28
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:31:20

US3732262

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:22:21

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:52:28
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:31:20

US3732262

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:22:21

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:52:28
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:31:20

US3732262

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:22:21

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:52:28
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:31:20

US3732262

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:22:21

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:52:28
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:31:20

US3732262

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:22:21

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:52:28
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:31:20

US3732262

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:22:21

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:52:28
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:31:20

US3732262

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:22:21

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:52:28
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:31:20

US3732262

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:22:21

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:52:28
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:31:20

US3732262

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:22:21

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:52:28
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:31:20

US3732262

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:22:21

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:52:28
User entered empty.	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:31:20

US3732262

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:22:21

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:31:20

US3732262

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:22:21

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:52:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:31:20

US3732262

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:52:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:31:20

US3732262

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:22:21

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:52:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:31:20

US3732262

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:22:21

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:52:28
User entered '1'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:31:20

US3732262

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:22:21

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:52:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:31:20

US3732262

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:22:21

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:31:20

US3732262

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:22:21

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:27:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:52:28
User entered empty.	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:31:20

US3732262

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:22:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:20:49
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:52:45
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	04 Sep 2020 18:33:06

US3732262

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:22:21

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:20:49
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:52:45
User entered '02 Sep 2020'	Lauren Arnett (b) (4)	04 Sep 2020 18:33:06

US3732262

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:20:49
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:52:45
User entered 'Clinic (Clinic)'	Lauren Arnett (b) (4)	04 Sep 2020 18:33:06

US3732262

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:22:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:20:49
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User entered 'VISIT1'	System	04 Sep 2020 18:33:06

US3732262

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:28
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:53:09
User entered '02 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 22:39:23

US3732262

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:22:21

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:28
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:53:09
User entered '111299'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 22:39:23

US3732262

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:22:21

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:28
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:53:09
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 22:39:23

US3732262

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:22:21

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:28
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:53:09
User closed query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 23:18:22
Query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' answered with 'complete ' (Site from DM).	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:33:36
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:33:28
User opened query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 12:52:33

US3732262

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:22:21

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:28
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:53:09
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:33:28

US3732262

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:22:21

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:28
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:53:09
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:33:28

US3732262

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:22:21

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:28
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:53:09
User entered 'No (N)'	Lauren Arnett (b) (4)	04 Sep 2020 18:33:28

US3732262

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:22:21

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:28
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:53:09
User entered 'No (N)'	Lauren Arnett (b) (4)	04 Sep 2020 18:33:28

US3732262

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:22:21

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:28
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:53:09
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 16:55:30
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:03:15
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:03:13

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:22:21

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:53:36
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 15:42:08
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' answered with 'Updated.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 16:54:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 16:54:33
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 14:30:33

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:22:21

Height

Audit	User	Time (GMT)
User entered empty.	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:35:00

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:22:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:53:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 16:54:41
User entered empty.	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:35:00

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:22:21

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:53:36
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 15:42:08
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' answered with 'Updated.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 16:54:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 16:54:33
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 14:30:33

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:22:21

Height

Audit	User	Time (GMT)
User entered empty.	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:35:00

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:22:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:53:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 16:54:41
User entered empty.	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:35:00

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User accepted default value 'Pre-Dose (PREDOSE)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:35:00

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:54:12
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	04 Sep 2020 18:35:00

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:54:12
User entered '02 Sep 2020'	Lauren Arnett (b) (4)	04 Sep 2020 18:35:00

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:54:12
User entered '15:09'	Lauren Arnett (b) (4)	04 Sep 2020 18:35:00

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User entered '02 Sep 2020 15:09'	System	04 Sep 2020 18:35:00

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:54:12
User entered '99.0' F	Lauren Arnett (b) (4)	04 Sep 2020 18:35:00

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:54:12
User entered 'Oral (Oral)'	Lauren Arnett (b) (4)	04 Sep 2020 18:35:00

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:54:12
User entered empty.	Lauren Arnett (b) (4)	04 Sep 2020 18:35:00

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:54:12
User entered '95'	Lauren Arnett (b) (4)	04 Sep 2020 18:35:00

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User entered 'bpm'	System	04 Sep 2020 18:35:00

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:54:12
User entered '14'	Lauren Arnett (b) (4)	04 Sep 2020 18:35:00

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User entered 'breaths/min'	System	04 Sep 2020 18:35:00

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:54:12
User entered '136'	Lauren Arnett (b) (4)	04 Sep 2020 18:35:00

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User entered 'mmHg'	System	04 Sep 2020 18:35:00

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:54:12
User entered '85'	Lauren Arnett (b) (4)	04 Sep 2020 18:35:00

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User entered 'mmHg'	System	04 Sep 2020 18:35:00

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:22:21

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:53:36
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 15:42:08
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' answered with 'Updated.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 16:54:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 16:54:33
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 14:30:33

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:22:21

Height

Audit	User	Time (GMT)
User entered empty.	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:35:00

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:22:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:53:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 16:54:41
User entered empty.	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:35:00

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User accepted default value 'Post-Dose (POSTDOSE)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:35:00

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:54:12
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	04 Sep 2020 18:35:00

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:54:12
User entered '02 Sep 2020'	Lauren Arnett (b) (4)	04 Sep 2020 18:35:00

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:54:12
User entered '16:47'	Lauren Arnett (b) (4)	04 Sep 2020 18:35:00

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User entered '02 Sep 2020 16:47'	System	04 Sep 2020 18:35:00

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:54:12
User closed query 'Temperature is not less than 38.0 C/100.4 F as required by protocol on day of first vaccination. Please confirm temperature is correct. (Exclusion criterion 4)' (Site from System).	(b) (4), (b) (6)	04 Sep 2020 23:18:46
Query 'Temperature is not less than 38.0 C/100.4 F as required by protocol on day of first vaccination. Please confirm temperature is correct. (Exclusion criterion 4)' answered with 'correct as is, as this is post-dose and post IP administration' (Site from System).	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:36:58
User opened query 'Temperature is not less than 38.0 System C/100.4 F as required by protocol on day of first vaccination. Please confirm temperature is correct. (Exclusion criterion 4)' (Site from System).		04 Sep 2020 18:35:00
User entered '100.5' F	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:35:00

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:54:12
User entered 'Oral (Oral)'	Lauren Arnett (b) (4)	04 Sep 2020 18:35:00

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:54:12
User entered empty.	Lauren Arnett (b) (4)	04 Sep 2020 18:35:00

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:54:12
User entered '92'	Lauren Arnett (b) (4)	04 Sep 2020 18:35:00

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User entered 'bpm'	System	04 Sep 2020 18:35:00

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:54:12
User entered '16'	Lauren Arnett (b) (4)	04 Sep 2020 18:35:00

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User entered 'breaths/min'	System	04 Sep 2020 18:35:00

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:54:12
User entered '122'	Lauren Arnett (b) (4)	04 Sep 2020 18:35:00

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User entered 'mmHg'	System	04 Sep 2020 18:35:00

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:54:12
User entered '93'	Lauren Arnett (b) (4)	04 Sep 2020 18:35:00

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User entered 'mmHg'	System	04 Sep 2020 18:35:00

US3732262

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:22:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:41
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:54:49
User entered 'No (N)'	Lauren Arnett (b) (4)	04 Sep 2020 18:37:10

US3732262

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:22:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:41
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:54:49
User entered empty.	Lauren Arnett (b) (4)	04 Sep 2020 18:37:10

US3732262

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:21

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:48
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:54:57
User entered 'No (N)'	Lauren Arnett (b) (4)	04 Sep 2020 18:37:14

US3732262

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:21

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:48
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:54:57
User entered empty.	Lauren Arnett (b) (4)	04 Sep 2020 18:37:14

US3732262

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:21

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:48
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:54:57
User entered empty.	Lauren Arnett (b) (4)	04 Sep 2020 18:37:14

US3732262

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:21

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:48
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:54:57
User entered empty.	Lauren Arnett (b) (4)	04 Sep 2020 18:37:14

US3732262

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:21

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:48
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:38:52
User closed query 'per CDM: please select yes or no for this field' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 04:11:49
Query 'per CDM: please select yes or no for this field answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 19:08:19
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 19:08:12
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 19:08:12
User opened query 'per CDM: please select yes or no for this field' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 15:22:15
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:54:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:37:14

US3732262

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:21

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:48
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:54:57
User entered empty.	Lauren Arnett (b) (4)	04 Sep 2020 18:37:14

US3732262

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:21

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:48
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:54:57
User entered empty.	Lauren Arnett (b) (4)	04 Sep 2020 18:37:14

US3732262

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:48
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User entered empty.	System	04 Sep 2020 18:37:14

US3732262

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:22:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:54
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:55:18
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	02 Sep 2020 23:19:12

US3732262

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:22:21

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:54
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:55:18
User entered empty.	Lauren Arnett (b) (4)	02 Sep 2020 23:19:12

US3732262

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:54
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:55:18
User entered empty.	Lauren Arnett (b) (4)	02 Sep 2020 23:19:12

US3732262

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:22:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:54
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User entered 'MRNA-1273 OR PLACEBO'	System	02 Sep 2020 23:19:12

US3732262

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:22:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:54
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:55:18
User entered '02 Sep 2020'	Lauren Arnett (b) (4)	02 Sep 2020 23:19:12

US3732262

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:22:21

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:54
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:55:18
User entered '16:17'	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 23:19:12

US3732262

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:22:21

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:54
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User entered '02 Sep 2020 16:17'	System	02 Sep 2020 23:19:12

US3732262

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:22:21

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:54
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:55:18
User entered 'Left Arm (LEFT ARM)'	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 23:19:12

US3732262

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:22:21

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:54
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:55:18
User entered 'ONCE'	System	02 Sep 2020 23:19:12

US3732262

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:22:21

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:21:54
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User entered 'INTRAMUSCULAR'	System	02 Sep 2020 23:19:12

US3732262

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:22:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:22:30
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:55:33
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	04 Sep 2020 18:37:30

US3732262

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:22:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:22:30
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:55:33
User entered '02 Sep 2020'	Lauren Arnett (b) (4)	04 Sep 2020 18:37:30

US3732262

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:22:21

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:22:30
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:55:33
User entered '15:59'	Lauren Arnett (b) (4)	04 Sep 2020 18:37:30

US3732262

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:22:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:22:30
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User entered '02 Sep 2020 15:59'	System	04 Sep 2020 18:37:30

US3732262

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:22:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:22:36
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:55:48
User entered '02 Sep 2020'	Lauren Arnett (b) (4)	04 Sep 2020 18:37:56

US3732262

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:22:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:22:36
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:37:56

US3732262

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:22:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:22:36
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:55:48
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	04 Sep 2020 18:37:56

US3732262

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:22:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:22:36
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:55:48
User entered '15:38'	Lauren Arnett (b) (4)	04 Sep 2020 18:37:56

US3732262

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:22:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:22:36
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User entered '02 Sep 2020 15:38'	System	04 Sep 2020 18:37:56

US3732262

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:22:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:22:36
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:37:56

US3732262

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:22:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:22:36
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:55:48
User entered 'No (N)'	Lauren Arnett (b) (4)	04 Sep 2020 18:37:56

US3732262

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:22:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:22:36
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:55:48
User entered empty.	Lauren Arnett (b) (4)	04 Sep 2020 18:37:56

US3732262

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:22:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:22:36
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User entered empty.	System	04 Sep 2020 18:37:56

US3732262

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:22:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:22:42
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:55:58
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	04 Sep 2020 18:38:02

US3732262

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:22:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:04:37
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:22:42
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:52:56
User entered 'I'	System	04 Sep 2020 18:38:02

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
Data entry locked.	System	02 Sep 2020 23:19:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:22:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T16:51:29', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'c4cad4be-3202-4c2f-99fb-5b9929540dd8' User entered 'Yes (Y)'	System	02 Sep 2020 23:53:11
	System	02 Sep 2020 23:53:11

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:22:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T16:52:09', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'c4cad4be-3202-4c2f-99fb-5b9929540dd8' User entered '100.5'	System	02 Sep 2020 23:53:11
	System	02 Sep 2020 23:53:11

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T16:53:01', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'c4cad4be-3202-4c2f-99fb-5b9929540dd8' User entered 'No (N)'	System	02 Sep 2020 23:53:11
	System	02 Sep 2020 23:53:11

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:22:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T16:53:08', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'c4cad4be-3202-4c2f-99fb-5b9929540dd8' User entered '02 Sep 2020 16:53'	System	02 Sep 2020 23:53:11
	System	02 Sep 2020 23:53:11

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:22:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '02 Sep 2020 16:37'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:22:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '02 Sep 2020 19:07'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
Data entry locked.	System	02 Sep 2020 23:19:12
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:22:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T22:23:19', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '4db8af9a-8776-4f17-af42-a2cf02fe6af4' User entered 'No (N)'	System	03 Sep 2020 05:23:43
	System	03 Sep 2020 05:23:43

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T22:23:24', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '4db8af9a-8776-4f17-af42-a2cf02fe6af4' User entered 'No (N)'	System	03 Sep 2020 05:23:43
	System	03 Sep 2020 05:23:43

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:22:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T22:23:40', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '4db8af9a-8776-4f17-af42-a2cf02fe6af4' User entered '02 Sep 2020 22:23'	System	03 Sep 2020 05:23:43
	System	03 Sep 2020 05:23:43

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:22:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '02 Sep 2020 20:02'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:22:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
Data entry locked.	System	02 Sep 2020 23:19:12
User entered 'Day 2'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:22:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-03T12:00:27', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1f8d0dea-e23b-47ea-80ad-366dc99897e9' User entered 'Yes (Y)'	System	03 Sep 2020 19:04:02
	System	03 Sep 2020 19:04:02

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:22:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-03T12:03:48', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1f8d0dea-e23b-47ea-80ad-366dc99897e9' User entered '99.5'	System	03 Sep 2020 19:04:02
	System	03 Sep 2020 19:04:02

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-03T12:03:53', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1f8d0dea-e23b-47ea-80ad-366dc99897e9' User entered 'No (N)'	System	03 Sep 2020 19:04:02
	System	03 Sep 2020 19:04:02

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:22:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-03T12:03:59', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1f8d0dea-e23b-47ea-80ad-366dc99897e9' User entered '03 Sep 2020 12:03'	System	03 Sep 2020 19:04:02
	System	03 Sep 2020 19:04:02

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:22:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:22:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
Data entry locked.	System	02 Sep 2020 23:19:12
User entered 'Day 3'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:22:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-04T16:01:56', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '64bd3200-4b3e-4da1-adba-9e6530ee17e2' User entered 'Yes (Y)'	System	04 Sep 2020 23:03:28
	System	04 Sep 2020 23:03:28

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:22:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-04T16:02:53', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '64bd3200-4b3e-4da1-adba-9e6530ee17e2' User entered '98.1'	System	04 Sep 2020 23:03:28
	System	04 Sep 2020 23:03:28

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-04T16:02:57', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '64bd3200-4b3e-4da1-adba-9e6530ee17e2' User entered 'Yes (Y)'	System	04 Sep 2020 23:03:28
	System	04 Sep 2020 23:03:28

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
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 'con meds updated for e-diary reported headache, does not meet reporting criteria for AE or true AR' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 13:33:29
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).	Lauren Arnett (b) (4)	11 Sep 2020 17:13:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-04T16:03:17', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '64bd3200-4b3e-4da1-adba-9e6530ee17e2'	System	04 Sep 2020 23:03:28
User entered '1'	System	04 Sep 2020 23:03:28

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:22:21

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-04T16:03:17', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '64bd3200-4b3e-4da1-adba-9e6530ee17e2' User entered '0'	System	04 Sep 2020 23:03:28
	System	04 Sep 2020 23:03:28

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:22:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-04T16:03:26', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '64bd3200-4b3e-4da1-adba-9e6530ee17e2' User entered '04 Sep 2020 16:03'	System	04 Sep 2020 23:03:28
	System	04 Sep 2020 23:03:28

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:22:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:22:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
Data entry locked.	System	02 Sep 2020 23:19:12
User entered 'Day 4'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:22:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-05T19:13:41', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '97ab81f0-d94b-4405-826a-4653ac2c61d7' User entered 'Yes (Y)'	System	06 Sep 2020 02:16:58
	System	06 Sep 2020 02:16:58

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:22:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-05T19:16:20', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '97ab81f0-d94b-4405-826a-4653ac2c61d7' User entered '98.4'	System	06 Sep 2020 02:16:58
	System	06 Sep 2020 02:16:58

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-05T19:16:50', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '97ab81f0-d94b-4405-826a-4653ac2c61d7' User entered 'No (N)'	System	06 Sep 2020 02:16:58
	System	06 Sep 2020 02:16:58

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:22:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-05T19:16:55', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '97ab81f0-d94b-4405-826a-4653ac2c61d7' User entered '05 Sep 2020 19:16'	System	06 Sep 2020 02:16:58
	System	06 Sep 2020 02:16:58

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:22:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:22:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
Data entry locked.	System	02 Sep 2020 23:19:12
User entered 'Day 5'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:22:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-06T13:19:36', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'cc55ef36-a1bd-4660-9e2a-df86eaf0c2ad' User entered 'Yes (Y)'	System	06 Sep 2020 20:24:34
	System	06 Sep 2020 20:24:34

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:22:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-06T13:24:22', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'cc55ef36-a1bd-4660-9e2a-df86eaf0c2ad' User entered '99.0'	System	06 Sep 2020 20:24:34
	System	06 Sep 2020 20:24:34

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-06T13:24:26', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'cc55ef36-a1bd-4660-9e2a-df86eaf0c2ad'	System	06 Sep 2020 20:24:34
User entered 'No (N)'	System	06 Sep 2020 20:24:34

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:22:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-06T13:24:31', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'cc55ef36-a1bd-4660-9e2a-df86eaf0c2ad' User entered '06 Sep 2020 13:24'	System	06 Sep 2020 20:24:34
	System	06 Sep 2020 20:24:34

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:22:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:22:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
Data entry locked.	System	02 Sep 2020 23:19:12
User entered 'Day 6'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:22:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-07T16:34:59', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'b5824645-8364-4201-9ad4-d7bc67b50e13'	System	07 Sep 2020 23:37:07
User entered 'Yes (Y)'	System	07 Sep 2020 23:37:07

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:22:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-07T16:36:53', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'b5824645-8364-4201-9ad4-d7bc67b50e13' User entered '98.3'	System	07 Sep 2020 23:37:07
	System	07 Sep 2020 23:37:07

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-07T16:36:57', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'b5824645-8364-4201-9ad4-d7bc67b50e13'	System	07 Sep 2020 23:37:07
User entered 'No (N)'	System	07 Sep 2020 23:37:07

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:22:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-07T16:37:00', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'b5824645-8364-4201-9ad4-d7bc67b50e13' User entered '07 Sep 2020 16:37'	System	07 Sep 2020 23:37:07
	System	07 Sep 2020 23:37:07

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:22:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:22:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
Data entry locked.	System	02 Sep 2020 23:19:12
User entered 'Day 7'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:22:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-08T17:21:01', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'ad76e484-162b-46db-8a7a-75b6d818887f' User entered 'Yes (Y)'	System	09 Sep 2020 00:22:25
	System	09 Sep 2020 00:22:25

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:22:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-08T17:22:06', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'ad76e484-162b-46db-8a7a-75b6d818887f' User entered '98.6'	System	09 Sep 2020 00:22:25
	System	09 Sep 2020 00:22:25

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-08T17:22:14', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'ad76e484-162b-46db-8a7a-75b6d818887f' User entered 'No (N)'	System	09 Sep 2020 00:22:25
	System	09 Sep 2020 00:22:25

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:22:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-08T17:22:21', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'ad76e484-162b-46db-8a7a-75b6d818887f' User entered '08 Sep 2020 17:22'	System	09 Sep 2020 00:22:25
	System	09 Sep 2020 00:22:25

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:22:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:22:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
Data entry locked.	System	02 Sep 2020 23:19:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:22:21

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 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T16:54:48', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'd8db92e3-769d-43f8-92b7-4a93d4665895'	System	02 Sep 2020 23:55:54
User entered 'Does not interfere with activity (2)'	System	02 Sep 2020 23:55:54

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:22:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T16:54:59', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'd8db92e3-769d-43f8-92b7-4a93d4665895' User entered 'No (N)'	System	02 Sep 2020 23:55:54
	System	02 Sep 2020 23:55:54

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T16:55:25', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'd8db92e3-769d-43f8-92b7-4a93d4665895' User entered 'No (N)'	System	02 Sep 2020 23:55:54
	System	02 Sep 2020 23:55:54

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:22:21

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 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T16:55:49', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'd8db92e3-769d-43f8-92b7-4a93d4665895'	System	02 Sep 2020 23:55:54
User entered 'Does not interfere with activity (2)'	System	02 Sep 2020 23:55:54

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:22:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T16:55:52', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'd8db92e3-769d-43f8-92b7-4a93d4665895'	System	02 Sep 2020 23:55:54
User entered '02 Sep 2020 16:55'	System	02 Sep 2020 23:55:54

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:22:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '02 Sep 2020 16:37'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:22:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '02 Sep 2020 19:07'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
Data entry locked.	System	02 Sep 2020 23:19:12
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:22:21

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 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T22:24:22', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '8c04f015-06ee-4f43-94e1-8efcbde2b194'	System	03 Sep 2020 05:25:04
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	03 Sep 2020 05:25:04

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:22:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T22:24:29', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '8c04f015-06ee-4f43-94e1-8efcbde2b194' User entered 'No (N)'	System	03 Sep 2020 05:25:04
	System	03 Sep 2020 05:25:04

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T22:24:34', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '8c04f015-06ee-4f43-94e1-8efcbde2b194' User entered 'No (N)'	System	03 Sep 2020 05:25:04
	System	03 Sep 2020 05:25:04

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:22:21

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 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T22:24:58', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '8c04f015-06ee-4f43-94e1-8efcbde2b194'	System	03 Sep 2020 05:25:04
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity (3)'	System	03 Sep 2020 05:25:04

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:22:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T22:25:02', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '8c04f015-06ee-4f43-94e1-8efcbde2b194' User entered '02 Sep 2020 22:25'	System	03 Sep 2020 05:25:04
	System	03 Sep 2020 05:25:04

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:22:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '02 Sep 2020 20:02'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:22:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
Data entry locked.	System	02 Sep 2020 23:19:12
User entered 'Day 2'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:22:21

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 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-03T12:46:02', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '36bce6f6-2dfe-46b1-9dde-6a5f86708443'	System	03 Sep 2020 19:46:48
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	03 Sep 2020 19:46:48

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:22:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-03T12:46:10', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '36bce6f6-2dfe-46b1-9dde-6a5f86708443' User entered 'No (N)'	System	03 Sep 2020 19:46:48
	System	03 Sep 2020 19:46:48

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-03T12:46:15', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '36bce6f6-2dfe-46b1-9dde-6a5f86708443' User entered 'No (N)'	System	03 Sep 2020 19:46:48
	System	03 Sep 2020 19:46:48

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:22:21

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 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-03T12:46:42', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '36bce6f6-2dfe-46b1-9dde-6a5f86708443'	System	03 Sep 2020 19:46:48
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity (3)'	System	03 Sep 2020 19:46:48

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:22:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-03T12:46:45', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '36bce6f6-2dfe-46b1-9dde-6a5f86708443'	System	03 Sep 2020 19:46:48
User entered '03 Sep 2020 12:46'	System	03 Sep 2020 19:46:48

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:22:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:22:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
Data entry locked.	System	02 Sep 2020 23:19:12
User entered 'Day 3'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:22:21

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 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-04T16:04:49', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'd329c3bc-9d41-4799-acbb-fead2725cd2c'	System	04 Sep 2020 23:05:38
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	04 Sep 2020 23:05:38

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:22:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-04T16:04:54', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'd329c3bc-9d41-4799-acbb-fead2725cd2c' User entered 'No (N)'	System	04 Sep 2020 23:05:38
	System	04 Sep 2020 23:05:38

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-04T16:04:59', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'd329c3bc-9d41-4799-acbb-fead2725cd2c' User entered 'No (N)'	System	04 Sep 2020 23:05:38
	System	04 Sep 2020 23:05:38

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:22:21

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 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-04T16:05:20', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'd329c3bc-9d41-4799-acbb-fead2725cd2c' User entered 'None (1)'	System	04 Sep 2020 23:05:38
	System	04 Sep 2020 23:05:38

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:22:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-04T16:05:35', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'd329c3bc-9d41-4799-acbb-fead2725cd2c' User entered '04 Sep 2020 16:05'	System	04 Sep 2020 23:05:38
	System	04 Sep 2020 23:05:38

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:22:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:22:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
Data entry locked.	System	02 Sep 2020 23:19:12
User entered 'Day 4'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:22:21

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 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-05T19:17:03', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'f69f78f9-eac5-4117-b2d6-b54692fa50d6' User entered 'None (1)'	System	06 Sep 2020 02:17:22
	System	06 Sep 2020 02:17:22

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:22:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-05T19:17:08', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'f69f78f9-eac5-4117-b2d6-b54692fa50d6' User entered 'No (N)'	System	06 Sep 2020 02:17:22
	System	06 Sep 2020 02:17:22

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-05T19:17:11', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'f69f78f9-eac5-4117-b2d6-b54692fa50d6' User entered 'No (N)'	System	06 Sep 2020 02:17:22
	System	06 Sep 2020 02:17:22

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:22:21

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 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-05T19:17:18', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'f69f78f9-eac5-4117-b2d6-b54692fa50d6' User entered 'None (1)'	System	06 Sep 2020 02:17:22
	System	06 Sep 2020 02:17:22

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:22:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-05T19:17:20', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'f69f78f9-eac5-4117-b2d6-b54692fa50d6' User entered '05 Sep 2020 19:17'	System	06 Sep 2020 02:17:22
	System	06 Sep 2020 02:17:22

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:22:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:22:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
Data entry locked.	System	02 Sep 2020 23:19:12
User entered 'Day 5'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:22:21

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 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-06T13:24:36', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '7d07fecd-d481-4a3b-9ad7-6056eb91101b' User entered 'None (1)'	System	06 Sep 2020 20:24:54
	System	06 Sep 2020 20:24:54

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:22:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-06T13:24:43', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '7d07fecd-d481-4a3b-9ad7-6056eb91101b' User entered 'No (N)'	System	06 Sep 2020 20:24:54
	System	06 Sep 2020 20:24:54

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-06T13:24:46', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '7d07fecd-d481-4a3b-9ad7-6056eb91101b' User entered 'No (N)'	System	06 Sep 2020 20:24:54
	System	06 Sep 2020 20:24:54

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:22:21

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 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-06T13:24:49', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '7d07fecd-d481-4a3b-9ad7-6056eb91101b' User entered 'None (1)'	System	06 Sep 2020 20:24:54
	System	06 Sep 2020 20:24:54

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:22:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-06T13:24:52', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '7d07fecd-d481-4a3b-9ad7-6056eb91101b' User entered '06 Sep 2020 13:24'	System	06 Sep 2020 20:24:54
	System	06 Sep 2020 20:24:54

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:22:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:22:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
Data entry locked.	System	02 Sep 2020 23:19:12
User entered 'Day 6'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:22:21

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 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-07T16:37:05', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '9a192026-9647-4d4c-b5da-f83295983002'	System	07 Sep 2020 23:37:25
User entered 'None (1)'	System	07 Sep 2020 23:37:25

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:22:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-07T16:37:10', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '9a192026-9647-4d4c-b5da-f83295983002' User entered 'No (N)'	System	07 Sep 2020 23:37:25
	System	07 Sep 2020 23:37:25

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-07T16:37:14', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '9a192026-9647-4d4c-b5da-f83295983002' User entered 'No (N)'	System	07 Sep 2020 23:37:25
	System	07 Sep 2020 23:37:25

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:22:21

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 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-07T16:37:20', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '9a192026-9647-4d4c-b5da-f83295983002'	System	07 Sep 2020 23:37:25
User entered 'None (1)'	System	07 Sep 2020 23:37:25

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:22:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-07T16:37:23', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '9a192026-9647-4d4c-b5da-f83295983002' User entered '07 Sep 2020 16:37'	System	07 Sep 2020 23:37:25
	System	07 Sep 2020 23:37:25

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:22:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:22:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
Data entry locked.	System	02 Sep 2020 23:19:12
User entered 'Day 7'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:22:21

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 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-08T13:32:19', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '251b301a-d496-458a-898c-26fbbdba447a' User entered 'None (1)'	System	08 Sep 2020 20:32:40
	System	08 Sep 2020 20:32:40

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:22:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-08T13:32:22', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '251b301a-d496-458a-898c-26fbbdba447a' User entered 'No (N)'	System	08 Sep 2020 20:32:40
	System	08 Sep 2020 20:32:40

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-08T13:32:26', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '251b301a-d496-458a-898c-26fbbdba447a' User entered 'No (N)'	System	08 Sep 2020 20:32:40
	System	08 Sep 2020 20:32:40

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:22:21

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 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-08T13:32:34', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '251b301a-d496-458a-898c-26fbbdba447a' User entered 'None (1)'	System	08 Sep 2020 20:32:40
	System	08 Sep 2020 20:32:40

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:22:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-08T13:32:38', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '251b301a-d496-458a-898c-26fbbdba447a' User entered '08 Sep 2020 13:32'	System	08 Sep 2020 20:32:40
	System	08 Sep 2020 20:32:40

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:22:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:22:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
Data entry locked.	System	02 Sep 2020 23:19:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:22:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T16:56:00', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '3fe1371c-7179-4604-821c-344667a6aa1a' User entered 'None (0)'	System	02 Sep 2020 23:56:41
	System	02 Sep 2020 23:56:41

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:22:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T16:56:05', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '3fe1371c-7179-4604-821c-344667a6aa1a' User entered 'None (0)'	System	02 Sep 2020 23:56:41
	System	02 Sep 2020 23:56:41

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:22:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T16:56:13', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '3fe1371c-7179-4604-821c-344667a6aa1a' User entered 'None (0)'	System	02 Sep 2020 23:56:41
	System	02 Sep 2020 23:56:41

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:22:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T16:56:17', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '3fe1371c-7179-4604-821c-344667a6aa1a' User entered 'None (0)'	System	02 Sep 2020 23:56:41
	System	02 Sep 2020 23:56:41

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:22:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T16:56:22', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '3fe1371c-7179-4604-821c-344667a6aa1a' User entered 'None (0)'	System	02 Sep 2020 23:56:41
	System	02 Sep 2020 23:56:41

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:22:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T16:56:24', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '3fe1371c-7179-4604-821c-344667a6aa1a' User entered 'None (0)'	System	02 Sep 2020 23:56:41
	System	02 Sep 2020 23:56:41

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T16:56:35', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '3fe1371c-7179-4604-821c-344667a6aa1a' User entered 'No (N)'	System	02 Sep 2020 23:56:41
	System	02 Sep 2020 23:56:41

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:22:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T16:56:38', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '3fe1371c-7179-4604-821c-344667a6aa1a' User entered '02 Sep 2020 16:56'	System	02 Sep 2020 23:56:41
	System	02 Sep 2020 23:56:41

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:22:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '02 Sep 2020 16:37'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:22:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '02 Sep 2020 19:07'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
Data entry locked.	System	02 Sep 2020 23:19:12
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:22:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T22:25:47', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '48adf5d3-898a-45fe-a60b-513f4d33e663'	System	03 Sep 2020 05:28:27
User entered 'No interference with activity (1)'	System	03 Sep 2020 05:28:27

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:22:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T22:26:07', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '48adf5d3-898a-45fe-a60b-513f4d33e663'	System	03 Sep 2020 05:28:27
User entered 'Some interference with activity (2)'	System	03 Sep 2020 05:28:27

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:22:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T22:26:29', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '48adf5d3-898a-45fe-a60b-513f4d33e663'	System	03 Sep 2020 05:28:27
User entered 'Some interference with activity (2)'	System	03 Sep 2020 05:28:27

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:22:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T22:27:43', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '48adf5d3-898a-45fe-a60b-513f4d33e663'	System	03 Sep 2020 05:28:27
User entered 'Some interference with activity (2)'	System	03 Sep 2020 05:28:27

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:22:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T22:27:52', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '48adf5d3-898a-45fe-a60b-513f4d33e663' User entered 'None (0)'	System	03 Sep 2020 05:28:27
	System	03 Sep 2020 05:28:27

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:22:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T22:28:04', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '48adf5d3-898a-45fe-a60b-513f4d33e663' User entered 'None (0)'	System	03 Sep 2020 05:28:27
	System	03 Sep 2020 05:28:27

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T22:28:22', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '48adf5d3-898a-45fe-a60b-513f4d33e663' User entered 'No (N)'	System	03 Sep 2020 05:28:27
	System	03 Sep 2020 05:28:27

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:22:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T22:28:25', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '48adf5d3-898a-45fe-a60b-513f4d33e663' User entered '02 Sep 2020 22:28'	System	03 Sep 2020 05:28:27
	System	03 Sep 2020 05:28:27

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:22:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '02 Sep 2020 20:02'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:22:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
Data entry locked.	System	02 Sep 2020 23:19:12
User entered 'Day 2'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:22:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-03T12:46:57', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1bb78657-d09d-454a-9759-5a6bf9bfacc4'	System	03 Sep 2020 19:47:57
User entered 'No interference with activity (1)'	System	03 Sep 2020 19:47:57

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:22:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-03T12:47:06', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1bb78657-d09d-454a-9759-5a6bf9bfacc4'	System	03 Sep 2020 19:47:57
User entered 'Some interference with activity (2)'	System	03 Sep 2020 19:47:57

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:22:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-03T12:47:15', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1bb78657-d09d-454a-9759-5a6bf9bfacc4' User entered 'Some interference with activity (2)'	System	03 Sep 2020 19:47:57
	System	03 Sep 2020 19:47:57

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:22:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-03T12:47:26', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1bb78657-d09d-454a-9759-5a6bf9bfacc4'	System	03 Sep 2020 19:47:57
User entered 'No interference with activity (1)'	System	03 Sep 2020 19:47:57

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:22:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-03T12:47:30', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1bb78657-d09d-454a-9759-5a6bf9bfacc4' User entered 'None (0)'	System	03 Sep 2020 19:47:57
	System	03 Sep 2020 19:47:57

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:22:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-03T12:47:33', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1bb78657-d09d-454a-9759-5a6bf9bfacc4' User entered 'None (0)'	System	03 Sep 2020 19:47:57
	System	03 Sep 2020 19:47:57

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-03T12:47:52', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1bb78657-d09d-454a-9759-5a6bf9bfacc4' User entered 'No (N)'	System	03 Sep 2020 19:47:57
	System	03 Sep 2020 19:47:57

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:22:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-03T12:47:55', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1bb78657-d09d-454a-9759-5a6bf9bfacc4' User entered '03 Sep 2020 12:47'	System	03 Sep 2020 19:47:57
	System	03 Sep 2020 19:47:57

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:22:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:22:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
Data entry locked.	System	02 Sep 2020 23:19:12
User entered 'Day 3'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:22:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-04T16:05:50', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '7a73a336-ea0b-4c5a-9ac7-23195f9889f0'	System	04 Sep 2020 23:08:18
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	04 Sep 2020 23:08:18

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:22:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-04T16:05:57', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '7a73a336-ea0b-4c5a-9ac7-23195f9889f0' User entered 'None (0)'	System	04 Sep 2020 23:08:18
	System	04 Sep 2020 23:08:18

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:22:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-04T16:06:03', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '7a73a336-ea0b-4c5a-9ac7-23195f9889f0' User entered 'None (0)'	System	04 Sep 2020 23:08:18
	System	04 Sep 2020 23:08:18

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:22:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-04T16:06:11', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '7a73a336-ea0b-4c5a-9ac7-23195f9889f0' User entered 'None (0)'	System	04 Sep 2020 23:08:18
	System	04 Sep 2020 23:08:18

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:22:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-04T16:06:15', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '7a73a336-ea0b-4c5a-9ac7-23195f9889f0' User entered 'None (0)'	System	04 Sep 2020 23:08:18
	System	04 Sep 2020 23:08:18

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:22:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-04T16:08:01', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '7a73a336-ea0b-4c5a-9ac7-23195f9889f0' User entered 'None (0)'	System	04 Sep 2020 23:08:18
	System	04 Sep 2020 23:08:18

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-04T16:08:07', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '7a73a336-ea0b-4c5a-9ac7-23195f9889f0' User entered 'No (N)'	System	04 Sep 2020 23:08:18
	System	04 Sep 2020 23:08:18

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:22:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-04T16:08:15', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '7a73a336-ea0b-4c5a-9ac7-23195f9889f0' User entered '04 Sep 2020 16:08'	System	04 Sep 2020 23:08:18
	System	04 Sep 2020 23:08:18

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:22:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:22:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
Data entry locked.	System	02 Sep 2020 23:19:12
User entered 'Day 4'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:22:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-05T19:17:36', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1eee1ee9-5d9d-48fb-91f8-f9770dc81364'	System	06 Sep 2020 02:18:26
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	06 Sep 2020 02:18:26

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:22:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-05T19:17:44', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1ee1ee9-5d9d-48fb-91f8-f9770dc81364' User entered 'None (0)'	System	06 Sep 2020 02:18:26
	System	06 Sep 2020 02:18:26

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:22:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-05T19:17:47', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1ee1ee9-5d9d-48fb-91f8-f9770dc81364' User entered 'None (0)'	System	06 Sep 2020 02:18:26
	System	06 Sep 2020 02:18:26

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:22:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-05T19:17:58', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1ee1ee9-5d9d-48fb-91f8-f9770dc81364' User entered 'None (0)'	System	06 Sep 2020 02:18:26
	System	06 Sep 2020 02:18:26

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:22:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-05T19:18:14', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1eee1ee9-5d9d-48fb-91f8-f9770dc81364'	System	06 Sep 2020 02:18:26
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	06 Sep 2020 02:18:26

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:22:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-05T19:18:18', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1ee1ee9-5d9d-48fb-91f8-f9770dc81364' User entered 'None (0)'	System	06 Sep 2020 02:18:26
	System	06 Sep 2020 02:18:26

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-05T19:18:21', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1ee1ee9-5d9d-48fb-91f8-f9770dc81364' User entered 'No (N)'	System	06 Sep 2020 02:18:26
	System	06 Sep 2020 02:18:26

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:22:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-05T19:18:24', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1ee1ee9-5d9d-48fb-91f8-f9770dc81364' User entered '05 Sep 2020 19:18'	System	06 Sep 2020 02:18:26
	System	06 Sep 2020 02:18:26

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:22:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:22:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
Data entry locked.	System	02 Sep 2020 23:19:12
User entered 'Day 5'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:22:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-06T13:25:07', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'ba9a3571-a382-4228-976f-256b1095ed4c'	System	06 Sep 2020 20:25:46
User entered 'No interference with activity (1)'	System	06 Sep 2020 20:25:46

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:22:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-06T13:25:16', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'ba9a3571-a382-4228-976f-256b1095ed4c' User entered 'None (0)'	System	06 Sep 2020 20:25:46
	System	06 Sep 2020 20:25:46

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:22:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-06T13:25:19', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'ba9a3571-a382-4228-976f-256b1095ed4c' User entered 'None (0)'	System	06 Sep 2020 20:25:46
	System	06 Sep 2020 20:25:46

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:22:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-06T13:25:20', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'ba9a3571-a382-4228-976f-256b1095ed4c' User entered 'None (0)'	System	06 Sep 2020 20:25:46
	System	06 Sep 2020 20:25:46

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:22:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-06T13:25:32', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'ba9a3571-a382-4228-976f-256b1095ed4c'	System	06 Sep 2020 20:25:46
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	06 Sep 2020 20:25:46

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:22:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-06T13:25:35', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'ba9a3571-a382-4228-976f-256b1095ed4c' User entered 'None (0)'	System	06 Sep 2020 20:25:46
	System	06 Sep 2020 20:25:46

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-06T13:25:39', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'ba9a3571-a382-4228-976f-256b1095ed4c' User entered 'No (N)'	System	06 Sep 2020 20:25:46
	System	06 Sep 2020 20:25:46

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:22:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-06T13:25:41', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'ba9a3571-a382-4228-976f-256b1095ed4c' User entered '06 Sep 2020 13:25'	System	06 Sep 2020 20:25:46
	System	06 Sep 2020 20:25:46

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:22:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:22:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
Data entry locked.	System	02 Sep 2020 23:19:12
User entered 'Day 6'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:22:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-07T16:37:36', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'c4299641-cdf7-43e7-a5fd-95fb79d4e54c'	System	07 Sep 2020 23:38:24
User entered 'No interference with activity (1)'	System	07 Sep 2020 23:38:24

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:22:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-07T16:37:47', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'c4299641-cdf7-43e7-a5fd-95fb79d4e54c' User entered 'None (0)'	System	07 Sep 2020 23:38:24
	System	07 Sep 2020 23:38:24

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:22:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-07T16:37:49', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'c4299641-cdf7-43e7-a5fd-95fb79d4e54c' User entered 'None (0)'	System	07 Sep 2020 23:38:24
	System	07 Sep 2020 23:38:24

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:22:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-07T16:37:52', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'c4299641-cdf7-43e7-a5fd-95fb79d4e54c' User entered 'None (0)'	System	07 Sep 2020 23:38:24
	System	07 Sep 2020 23:38:24

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:22:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-07T16:37:56', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'c4299641-cdf7-43e7-a5fd-95fb79d4e54c' User entered 'None (0)'	System	07 Sep 2020 23:38:24
	System	07 Sep 2020 23:38:24

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:22:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-07T16:38:02', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'c4299641-cdf7-43e7-a5fd-95fb79d4e54c' User entered 'None (0)'	System	07 Sep 2020 23:38:24
	System	07 Sep 2020 23:38:24

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-07T16:38:16', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'c4299641-cdf7-43e7-a5fd-95fb79d4e54c' User entered 'No (N)'	System	07 Sep 2020 23:38:24
	System	07 Sep 2020 23:38:24

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:22:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-07T16:38:19', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'c4299641-cdf7-43e7-a5fd-95fb79d4e54c' User entered '07 Sep 2020 16:38'	System	07 Sep 2020 23:38:24
	System	07 Sep 2020 23:38:24

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:22:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:22:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
Data entry locked.	System	02 Sep 2020 23:19:12
User entered 'Day 7'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:22:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-08T13:32:42', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '109f25a4-c2d8-4d36-83c9-378c119aa4f4' User entered 'None (0)'	System	08 Sep 2020 20:33:22
	System	08 Sep 2020 20:33:22

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:22:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-08T13:32:47', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '109f25a4-c2d8-4d36-83c9-378c119aa4f4' User entered 'None (0)'	System	08 Sep 2020 20:33:22
	System	08 Sep 2020 20:33:22

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:22:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-08T13:32:53', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '109f25a4-c2d8-4d36-83c9-378c119aa4f4' User entered 'None (0)'	System	08 Sep 2020 20:33:22
	System	08 Sep 2020 20:33:22

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:22:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-08T13:32:59', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '109f25a4-c2d8-4d36-83c9-378c119aa4f4' User entered 'None (0)'	System	08 Sep 2020 20:33:22
	System	08 Sep 2020 20:33:22

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:22:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-08T13:33:03', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '109f25a4-c2d8-4d36-83c9-378c119aa4f4' User entered 'None (0)'	System	08 Sep 2020 20:33:22
	System	08 Sep 2020 20:33:22

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:22:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-08T13:33:11', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '109f25a4-c2d8-4d36-83c9-378c119aa4f4' User entered 'None (0)'	System	08 Sep 2020 20:33:22
	System	08 Sep 2020 20:33:22

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-08T13:33:17', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '109f25a4-c2d8-4d36-83c9-378c119aa4f4' User entered 'No (N)'	System	08 Sep 2020 20:33:22
	System	08 Sep 2020 20:33:22

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:22:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-08T13:33:19', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '109f25a4-c2d8-4d36-83c9-378c119aa4f4' User entered '08 Sep 2020 13:33'	System	08 Sep 2020 20:33:22
	System	08 Sep 2020 20:33:22

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:22:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 23:19:12

US3732262

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:22:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 23:19:12

US3732262

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:20:43
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:57:06
User entered 'Yes (Y)'	Linda Vega (b) (4)	10 Sep 2020 16:33:21

US3732262

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:20:43
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:57:06
User entered '09 Sep 2020'	Linda Vega (b) (4)	10 Sep 2020 16:33:21

US3732262

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:20:43
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:57:06
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4)	10 Sep 2020 16:33:21

US3732262

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:20:43
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:57:06
User entered empty.	Linda Vega (b) (4)	10 Sep 2020 16:33:21

US3732262

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:20:43
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:42:04
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:57:15
User entered 'Yes (Y)'	Linda Vega (b) (4)	10 Sep 2020 16:33:24

US3732262

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:20:43
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:42:04
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
User entered 'l'	System	10 Sep 2020 16:33:24

US3732262

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:39:10
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:42:17
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 22:32:49
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 22:45:06
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:39:28
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 18:56:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 18:56:59
User entered 'No (N)' reason for change: Data Entry Error	Lauren Arnett (b) (4) (b) (4)	27 Oct 2020 18:56:59
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 18:55:38
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	27 Oct 2020 18:55:38
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 18:55:38
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	27 Oct 2020 18:55:15
User entered 'No (N)'	(b) (4), (b) (6)	27 Oct 2020 18:55:15

US3732262

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:39:10
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:42:17
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:32:49
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 22:45:06
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:39:28
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 18:55:15

US3732262

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:39:10
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:42:17
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:32:49
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 22:45:06
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:39:28
User entered empty; reason for change Data Entry Error	Lauren Arnett (b) (4)	27 Oct 2020 18:56:59
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	27 Oct 2020 18:55:15

US3732262

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:39:10
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:42:17
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:32:49
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 22:45:06
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:39:28
User entered 'Visit will be omitted due to Convalescent Period.'	(b) (4), (b) (6)	27 Oct 2020 18:55:15

US3732262

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:39:10
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:42:22
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:32:55
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 22:45:14
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:39:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 18:57:48

US3732262

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:39:10
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:42:22
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
User entered 'l'	System	27 Oct 2020 18:57:48

US3732262

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:30
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:42:36
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:33:19
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 22:45:24
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:39:52
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 18:57:25

US3732262

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:30
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:42:36
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:33:19
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 22:45:24
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:39:52
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 18:57:25

US3732262

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:30
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:42:36
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:33:19
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 22:45:24
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:39:52
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 18:57:25

US3732262

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:30
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:42:36
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 23:09:00
User entered 'Subject was in the Convalescent phase' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 22:46:17
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 22:33:31
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:33:19
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 22:45:24
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:39:52
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 18:57:25

US3732262

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:30
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:42:43
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 23:09:07
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 22:45:32
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:39:58
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Nov 2020 18:57:53
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 18:57:12

US3732262

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:30
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:42:43
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
User entered 'l'	System	04 Nov 2020 18:57:53
User entered empty.	System	04 Nov 2020 18:57:12

US3732262

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:22:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 23:11:06
User closed query 'Per CDM: As per CCGs p. 18 Scenario 4: Vital Signs Dosing, Physical Examination, Exposure and Immunogenicity Assessment forms should be completed accordingly. Kindly review and reconcile as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 15:08:35
Query 'Per CDM: As per CCGs p. 18 Scenario 4: Vital Signs Dosing, Physical Examination, Exposure and Immunogenicity Assessment forms should be completed accordingly. Kindly review and reconcile as appropriate. ' answered with 'Correct as is. Visit not completed as subject entered into the Convalescent Phase ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 23:49:20
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 22:45:43
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:41:01
User opened query 'Per CDM: As per CCGs p. 18 Scenario 4: Vital Signs Dosing, Physical Examination, Exposure and Immunogenicity Assessment forms should be completed accordingly. Kindly review and reconcile as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 13:33:02
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 18:58:04

US3732262

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 23:11:06
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 22:45:43
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:41:01
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 18:58:04

US3732262

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 23:11:06
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 22:45:43
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:41:01
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 18:58:04

US3732262

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:22:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
User entered 'VISIT2'	System	04 Nov 2020 18:58:04

US3732262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:22:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:28:51
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
User entered 'No (N)'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	11 Jan 2021 21:12:05

US3732262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:22:21

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:28:51
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
User entered 'Confirmed COVID-19 (COVID)'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	11 Jan 2021 21:12:05

US3732262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:28:51
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
User entered empty.	(b) (4) Amara Yilmaz (b) (4) (b) (4)	11 Jan 2021 21:12:05

US3732262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:22:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
User entered empty.	System	11 Jan 2021 21:12:05

US3732262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:22:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:28:51
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
User entered empty.	(b) (4) Amara Yilmaz (b) (4) (b) (4)	11 Jan 2021 21:12:05

US3732262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:22:21

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:28:51
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
User entered empty.	(b) (4) Amara Yilmaz (b) (4) (b) (4)	11 Jan 2021 21:12:05

US3732262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:22:21

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
User entered empty.	System	11 Jan 2021 21:12:05

US3732262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:22:21

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:28:51
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
User entered empty.	(b) (4) Amara Yilmaz (b) (4) (b) (4)	11 Jan 2021 21:12:05

US3732262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:22:21

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:28:51
User entered empty.	System	11 Jan 2021 21:12:05

US3732262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:22:21

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
User entered empty.	System	11 Jan 2021 21:12:05

US3732262

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4)	09 Nov 2020 23:11:42
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 22:46:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:41:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 18:58:17

US3732262

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:17
User entered '1'	System	04 Nov 2020 18:58:17

US3732262

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:11
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:42:58
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 23:32:30
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 22:46:40
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:41:42
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 19:12:08

US3732262

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:11
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:42:58
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 23:32:30
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 22:46:40
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:41:42
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 19:12:08

US3732262

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:11
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:42:58
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 23:32:30
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 22:46:40
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:41:42
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 19:12:08

US3732262

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:11
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:42:58
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 23:32:30
User entered 'Subject was in the Convalescent Phase' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 23:17:09
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 22:46:40
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:41:42
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 19:12:08

US3732262

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:11
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:43:03
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 23:32:36
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 22:46:51
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:41:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 19:12:02

US3732262

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:11
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:43:03
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
User entered 'l'	System	04 Nov 2020 19:12:02

US3732262

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:00
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:43:17
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:35:05
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 22:47:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:42:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 19:12:34

US3732262

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:00
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:43:17
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:35:05
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 22:47:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:42:15
User entered '15 Oct 2020'	(b) (4), (b) (6)	04 Nov 2020 19:12:34

US3732262

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:00
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:43:17
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:35:05
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 22:47:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:42:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	04 Nov 2020 19:12:34

US3732262

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:00
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:43:17
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:35:05
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 22:47:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:42:15
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 19:12:34

US3732262

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:00
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:43:23
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:35:11
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 22:47:08
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:42:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 19:12:39

US3732262

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:00
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:43:23
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
User entered 'I'	System	04 Nov 2020 19:12:39

US3732262

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:23:24
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:43:35
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:35:35
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 19:12:52

US3732262

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:23:24
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:43:35
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:35:35
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
	(b) (4)	
User entered '22 Oct 2020'	(b) (4), (b) (6)	04 Nov 2020 19:12:52

US3732262

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:23:24
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:43:35
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:35:35
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	04 Nov 2020 19:12:52

US3732262

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:23:24
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:43:35
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:35:35
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 19:12:52

US3732262

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:23:24
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:43:40
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:35:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 19:12:56

US3732262

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:23:24
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:43:40
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
User entered 'I'	System	04 Nov 2020 19:12:56

US3732262

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:22:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:41:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:35:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	05 Nov 2020 19:26:57

US3732262

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:41:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:35:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
User entered '04 Nov 2020'	Lauren Arnett (b) (4)	05 Nov 2020 19:26:57

US3732262

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:41:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:35:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
User entered 'Clinic (Clinic)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	05 Nov 2020 19:26:57

US3732262

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:22:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:41:00
User entered 'VISIT3'	System	05 Nov 2020 19:26:57

US3732262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:41:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:36:21
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
User entered 'Yes (Y)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	05 Nov 2020 19:27:27

US3732262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:41:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:36:21
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
User entered '04 Nov 2020'	(b) (4) Lauren Arnett (b) (4) (b) (4)	05 Nov 2020 19:27:27

US3732262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:41:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:36:21
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
User entered '14:38'	(b) (4) Lauren Arnett (b) (4) (b) (4)	05 Nov 2020 19:27:27

US3732262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:41:00
User entered '04 Nov 2020 14:38'	System	05 Nov 2020 19:27:27

US3732262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:41:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:36:21
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
User entered '99.2' F	(b) (4) Lauren Arnett (b) (4) (b) (4)	05 Nov 2020 19:27:27

US3732262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:41:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:36:21
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
User entered 'Oral (Oral)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	05 Nov 2020 19:27:27

US3732262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:41:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:36:21
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
User entered empty.	(b) (4) Lauren Arnett (b) (4) (b) (4)	05 Nov 2020 19:27:27

US3732262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:41:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:36:21
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
User entered '86'	(b) (4) Lauren Arnett (b) (4) (b) (4)	05 Nov 2020 19:27:27

US3732262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:41:00
User entered 'bpm'	System	05 Nov 2020 19:27:27

US3732262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:41:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:36:21
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
User entered '16'	(b) (4) Lauren Arnett (b) (4) (b) (4)	05 Nov 2020 19:27:27

US3732262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:41:00
User entered 'breaths/min'	System	05 Nov 2020 19:27:27

US3732262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:41:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:36:21
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
User entered '134'	(b) (4) Lauren Arnett (b) (4) (b) (4)	05 Nov 2020 19:27:27

US3732262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:41:00
User entered 'mmHg'	System	05 Nov 2020 19:27:27

US3732262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:41:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:36:21
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
User entered '88'	(b) (4) Lauren Arnett (b) (4) (b) (4)	05 Nov 2020 19:27:27

US3732262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:41:00
User entered 'mmHg'	System	05 Nov 2020 19:27:27

US3732262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:41:00

US3732262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:41:00

US3732262

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:22:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:41:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:36:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
User entered 'Yes (Y)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	05 Nov 2020 19:27:39

US3732262

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:22:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:41:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:36:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
User entered '04 Nov 2020'	(b) (4) Lauren Arnett (b) (4) (b) (4)	05 Nov 2020 19:27:39

US3732262

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:22:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:41:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:37:21
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	05 Nov 2020 19:27:52

US3732262

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:22:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:41:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:37:21
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
User entered '04 Nov 2020'	(b) (4) Lauren Arnett (b) (4) (b) (4)	05 Nov 2020 19:27:52

US3732262

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:22:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:41:00
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:37:21
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
User entered '14:52'	(b) (4) Lauren Arnett (b) (4) (b) (4)	05 Nov 2020 19:27:52

US3732262

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:22:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:41:00
User entered '04 Nov 2020 14:52'	System	05 Nov 2020 19:27:52

US3732262

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:41:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:56:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
User entered 'Yes (Y)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	05 Nov 2020 19:28:06

US3732262

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:41:00
User entered '1'	System	05 Nov 2020 19:28:06

US3732262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
Data entry locked.	System	02 Sep 2020 23:19:12
User entered 'Day 64'	System	02 Sep 2020 23:19:12

US3732262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-11-05T17:59:29', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'd40fb24f-e586-4dcb-9be4-73fae9ab2071' User entered 'No (N)'	System	06 Nov 2020 02:00:25
	System	06 Nov 2020 02:00:25

US3732262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-11-05T17:59:52', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'd40fb24f-e586-4dcb-9be4-73fae9ab2071'	System	06 Nov 2020 02:00:25
User entered 'No (N)'	System	06 Nov 2020 02:00:25

US3732262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-11-05T18:00:22', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'd40fb24f-e586-4dcb-9be4-73fae9ab2071' User entered '05 Nov 2020 18:00:22'	System	06 Nov 2020 02:00:25
	System	06 Nov 2020 02:00:25

US3732262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
Data entry locked.	System	02 Sep 2020 23:19:12
User entered '02 Nov 2020 00:01'	System	02 Sep 2020 23:19:12

US3732262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
Data entry locked.	System	02 Sep 2020 23:19:12
User entered '06 Nov 2020 23:59'	System	02 Sep 2020 23:19:12

US3732262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
Data entry locked.	System	02 Sep 2020 23:19:12
User entered 'Day 71'	System	02 Sep 2020 23:19:12

US3732262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-11-09T02:45:39', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'a9c67db1-3725-4e37-938b-f5d58d2001c8' User entered 'No (N)'	System	09 Nov 2020 10:45:55
	System	09 Nov 2020 10:45:55

US3732262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-11-09T02:44:51', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'a9c67db1-3725-4e37-938b-f5d58d2001c8' User entered 'No (N)'	System	09 Nov 2020 10:45:55
	System	09 Nov 2020 10:45:55

US3732262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-11-09T02:45:52', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'a9c67db1-3725-4e37-938b-f5d58d2001c8' User entered '09 Nov 2020 02:45:52'	System	09 Nov 2020 10:45:55
	System	09 Nov 2020 10:45:55

US3732262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
Data entry locked.	System	02 Sep 2020 23:19:12
User entered '09 Nov 2020 00:01'	System	02 Sep 2020 23:19:12

US3732262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
Data entry locked.	System	02 Sep 2020 23:19:12
User entered '13 Nov 2020 23:59'	System	02 Sep 2020 23:19:12

US3732262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
Data entry locked.	System	02 Sep 2020 23:19:12
User entered 'Day 78'	System	02 Sep 2020 23:19:12

US3732262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-11-16T00:01:21', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '996fe8cb-a662-4689-812c-08530925071b' User entered 'No (N)'	System	16 Nov 2020 08:01:49
	System	16 Nov 2020 08:01:49

US3732262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-11-16T00:01:31', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '996fe8cb-a662-4689-812c-08530925071b' User entered 'No (N)'	System	16 Nov 2020 08:01:49
	System	16 Nov 2020 08:01:49

US3732262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-11-16T00:01:46', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '996fe8cb-a662-4689-812c-08530925071b' User entered '16 Nov 2020 00:01:46'	System	16 Nov 2020 08:01:49
	System	16 Nov 2020 08:01:49

US3732262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
Data entry locked.	System	02 Sep 2020 23:19:12
User entered '16 Nov 2020 00:01'	System	02 Sep 2020 23:19:12

US3732262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:52:18
Data entry locked.	System	02 Sep 2020 23:19:12
User entered '20 Nov 2020 23:59'	System	02 Sep 2020 23:19:12

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-11-30T00:03:52', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '29f3f1ab-a405-4d4c-a54b-76c69d2ed8e2'	System	30 Nov 2020 08:04:20
User entered 'No (N)'	System	30 Nov 2020 08:04:20

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-11-30T00:04:03', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '29f3f1ab-a405-4d4c-a54b-76c69d2ed8e2'	System	30 Nov 2020 08:04:20
User entered 'No (N)'	System	30 Nov 2020 08:04:20

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-11-30T00:04:11', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '29f3f1ab-a405-4d4c-a54b-76c69d2ed8e2' User entered '30 Nov 2020 00:04:11'	System	30 Nov 2020 08:04:20
	System	30 Nov 2020 08:04:20

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-12-04T01:15:27', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '8d89f48f-915d-47f2-9f09-0271f18a15f7'	System	04 Dec 2020 09:15:50
User entered 'No (N)'	System	04 Dec 2020 09:15:50

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-12-04T01:15:35', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '8d89f48f-915d-47f2-9f09-0271f18a15f7'	System	04 Dec 2020 09:15:50
User entered 'No (N)'	System	04 Dec 2020 09:15:50

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-12-04T01:15:43', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '8d89f48f-915d-47f2-9f09-0271f18a15f7' User entered '04 Dec 2020 01:15:43'	System	04 Dec 2020 09:15:50
	System	04 Dec 2020 09:15:50

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-12-11T15:18:49', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'bf435be5-4f3a-43d1-969a-79afbe63071c'	System	11 Dec 2020 23:19:06
User entered 'No (N)'	System	11 Dec 2020 23:19:06

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-12-11T15:19:00', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'bf435be5-4f3a-43d1-969a-79afbe63071c'	System	11 Dec 2020 23:19:06
User entered 'No (N)'	System	11 Dec 2020 23:19:06

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-12-11T15:19:03', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'bf435be5-4f3a-43d1-969a-79afbe63071c' User entered '11 Dec 2020 15:19:03'	System	11 Dec 2020 23:19:06
	System	11 Dec 2020 23:19:06

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-12-18T00:52:10', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '68a63eb2-e3a2-48c8-9cca-92ddeba6b361'	System	18 Dec 2020 08:52:26
User entered 'No (N)'	System	18 Dec 2020 08:52:26

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-12-18T00:52:16', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '68a63eb2-e3a2-48c8-9cca-92ddeba6b361' User entered 'No (N)'	System	18 Dec 2020 08:52:26

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-12-18T00:52:25', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '68a63eb2-e3a2-48c8-9cca-92ddeba6b361' User entered '18 Dec 2020 00:52:25'	System	18 Dec 2020 08:52:26
	System	18 Dec 2020 08:52:26

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-12-25T05:57:16', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '5472e5ee-e05a-4533-bb4f-7036acb893b2' User entered 'No (N)'	System	25 Dec 2020 13:57:51
	System	25 Dec 2020 13:57:51

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-12-25T05:57:45', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '5472e5ee-e05a-4533-bb4f-7036acb893b2' User entered 'No (N)'	System	25 Dec 2020 13:57:51
	System	25 Dec 2020 13:57:51

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-12-25T05:57:49', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '5472e5ee-e05a-4533-bb4f-7036acb893b2' User entered '25 Dec 2020 05:57:49'	System	25 Dec 2020 13:57:51
	System	25 Dec 2020 13:57:51

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-01-01T16:52:07', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'fd2b8e17-089c-4e42-b821-0e594f88e967'	System	02 Jan 2021 00:53:38
User entered 'No (N)'	System	02 Jan 2021 00:53:38

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-01-01T16:53:28', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'fd2b8e17-089c-4e42-b821-0e594f88e967'	System	02 Jan 2021 00:53:38
User entered 'No (N)'	System	02 Jan 2021 00:53:38

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-01-01T16:53:36', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'fd2b8e17-089c-4e42-b821-0e594f88e967'	System	02 Jan 2021 00:53:38
User entered '01 Jan 2021 16:53:36'	System	02 Jan 2021 00:53:38

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-01-08T08:09:46', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '720cfe56-50c4-4586-a71a-aa54d6a455bc' User entered 'No (N)'	System	08 Jan 2021 16:10:08
	System	08 Jan 2021 16:10:08

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-01-08T08:09:59', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '720cfe56-50c4-4586-a71a-aa54d6a455bc' User entered 'No (N)'	System	08 Jan 2021 16:10:08

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-01-08T08:10:02', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '720cfe56-50c4-4586-a71a-aa54d6a455bc' User entered '08 Jan 2021 08:10:02'	System	08 Jan 2021 16:10:08
	System	08 Jan 2021 16:10:08

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-01-15T16:50:10', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'fb1a9ae0-895e-4bc4-abea-0cb57b3eb491' User entered 'No (N)'	System	16 Jan 2021 00:50:22
	System	16 Jan 2021 00:50:22

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-01-15T16:50:16', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'fb1a9ae0-895e-4bc4-abea-0cb57b3eb491' User entered 'No (N)'	System	16 Jan 2021 00:50:22
	System	16 Jan 2021 00:50:22

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-01-15T16:50:19', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'fb1a9ae0-895e-4bc4-abea-0cb57b3eb491' User entered '15 Jan 2021 16:50:19'	System	16 Jan 2021 00:50:22

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-01-22T00:38:04', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '21ca180d-c6d8-46ae-bced-4a12529ad310'	System	22 Jan 2021 08:38:21
User entered 'No (N)'	System	22 Jan 2021 08:38:21

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-01-22T00:38:15', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '21ca180d-c6d8-46ae-bced-4a12529ad310'	System	22 Jan 2021 08:38:21
User entered 'No (N)'	System	22 Jan 2021 08:38:21

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-01-22T00:38:19', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '21ca180d-c6d8-46ae-bced-4a12529ad310' User entered '22 Jan 2021 00:38:19'	System	22 Jan 2021 08:38:21
	System	22 Jan 2021 08:38:21

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-01-29T02:39:42', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '0935ed5d-d928-4740-a015-e92e0f4c11cf' User entered 'No (N)'	System	29 Jan 2021 10:40:03
	System	29 Jan 2021 10:40:03

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-01-29T02:39:54', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '0935ed5d-d928-4740-a015-e92e0f4c11cf' User entered 'No (N)'	System	29 Jan 2021 10:40:03
	System	29 Jan 2021 10:40:03

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-01-29T02:39:58', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '0935ed5d-d928-4740-a015-e92e0f4c11cf' User entered '29 Jan 2021 02:39:58'	System	29 Jan 2021 10:40:03
	System	29 Jan 2021 10:40:03

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-02-06T18:18:18', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'fe4ef472-0195-4df6-9789-323c5a08e5ca' User entered 'No (N)'	System	07 Feb 2021 02:19:38
	System	07 Feb 2021 02:19:38

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-02-06T18:18:21', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'fe4ef472-0195-4df6-9789-323c5a08e5ca' User entered 'No (N)'	System	07 Feb 2021 02:19:38

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-02-06T18:18:24', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'fe4ef472-0195-4df6-9789-323c5a08e5ca' User entered '06 Feb 2021 18:18:24'	System	07 Feb 2021 02:19:38
	System	07 Feb 2021 02:19:38

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-02-13T18:39:33', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '33158acf-1e35-4c9c-bebd-ec0dd541dfee' User entered 'No (N)'	System	14 Feb 2021 02:39:47

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-02-13T18:39:40', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '33158acf-1e35-4c9c-bebd-ec0dd541dfee' User entered 'No (N)'	System	14 Feb 2021 02:39:47

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-02-13T18:39:45', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '33158acf-1e35-4c9c-bebd-ec0dd541dfee' User entered '13 Feb 2021 18:39:45'	System	14 Feb 2021 02:39:47

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-02-21T08:57:26', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '049054d9-0cfd-4f86-b1d4-a24aeccfbdf5' User entered 'No (N)'	System	21 Feb 2021 16:57:36
	System	21 Feb 2021 16:57:36

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-02-21T08:57:29', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '049054d9-0cfd-4f86-b1d4-a24aeccfbdf5' User entered 'No (N)'	System	21 Feb 2021 16:57:36

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-02-21T08:57:32', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '049054d9-0cfd-4f86-b1d4-a24aeccfbdf5' User entered '21 Feb 2021 08:57:32'	System	21 Feb 2021 16:57:36
	System	21 Feb 2021 16:57:36

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-02-26T00:03:26-08:00', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1902646f-0e9e-44e7-be6d-fe6e3eb66e43'	System	26 Feb 2021 08:03:42
User entered 'No (N)'	System	26 Feb 2021 08:03:42

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-02-26T00:03:34-08:00', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1902646f-0e9e-44e7-be6d-fe6e3eb66e43'	System	26 Feb 2021 08:03:42
User entered 'No (N)'	System	26 Feb 2021 08:03:42

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-02-26T00:03:39-08:00', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1902646f-0e9e-44e7-be6d-fe6e3eb66e43'	System	26 Feb 2021 08:03:42
User entered '26 Feb 2021 08:03:39'	System	26 Feb 2021 08:03:42

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-03-07T12:00:31-08:00', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '5cc7208f-7299-4342-941b-180e44a4a68b'	System	07 Mar 2021 20:00:49
User entered 'No (N)'	System	07 Mar 2021 20:00:49

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-03-07T12:00:42-08:00', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '5cc7208f-7299-4342-941b-180e44a4a68b' User entered 'No (N)'	System	07 Mar 2021 20:00:49

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-03-07T12:00:46-08:00', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '5cc7208f-7299-4342-941b-180e44a4a68b' User entered '07 Mar 2021 12:00:46'	System	07 Mar 2021 20:00:49
	System	07 Mar 2021 20:00:49

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-03-12T01:28:57-08:00', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '7904fdd9-ff97-443d-8d8a-09952c5724ea'	System	14 Mar 2021 21:00:14
User entered 'No (N)'	System	14 Mar 2021 21:00:14

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-03-14T13:59:55-07:00', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '7904fdd9-ff97-443d-8d8a-09952c5724ea'	System	14 Mar 2021 21:00:14
User entered 'No (N)'	System	14 Mar 2021 21:00:14

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-03-14T14:00:10-07:00', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '7904fdd9-ff97-443d-8d8a-09952c5724ea' User entered '14 Mar 2021 14:00:10'	System	14 Mar 2021 21:00:14
	System	14 Mar 2021 21:00:14

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-03-19T01:51:47-07:00', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '7e59c289-bfb2-4479-8428-334a047fd226'	System	19 Mar 2021 08:52:18
User entered 'No (N)'	System	19 Mar 2021 08:52:18

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-03-19T01:52:14-07:00', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '7e59c289-bfb2-4479-8428-334a047fd226'	System	19 Mar 2021 08:52:18
User entered 'No (N)'	System	19 Mar 2021 08:52:18

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-03-19T01:52:17-07:00', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '7e59c289-bfb2-4479-8428-334a047fd226' User entered '19 Mar 2021 01:52:17'	System	19 Mar 2021 08:52:18
	System	19 Mar 2021 08:52:18

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-03-26T01:03:20-07:00', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '2d7f1e0c-3364-40f2-a8e9-2e1d2a414d86'	System	26 Mar 2021 08:03:34
User entered 'No (N)'	System	26 Mar 2021 08:03:34

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-03-26T01:03:27-07:00', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '2d7f1e0c-3364-40f2-a8e9-2e1d2a414d86'	System	26 Mar 2021 08:03:34
User entered 'No (N)'	System	26 Mar 2021 08:03:34

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-03-26T01:03:31-07:00', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '2d7f1e0c-3364-40f2-a8e9-2e1d2a414d86' User entered '26 Mar 2021 01:03:31'	System	26 Mar 2021 08:03:34
	System	26 Mar 2021 08:03:34

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-04-04T12:00:18-07:00', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '517a8d8e-f845-41ee-b4ab-45617a14b7c8' User entered 'No (N)'	System	04 Apr 2021 19:00:29
	System	04 Apr 2021 19:00:29

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-04-04T12:00:21-07:00', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '517a8d8e-f845-41ee-b4ab-45617a14b7c8' User entered 'No (N)'	System	04 Apr 2021 19:00:29

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-04-04T12:00:26-07:00', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '517a8d8e-f845-41ee-b4ab-45617a14b7c8' User entered '04 Apr 2021 12:00:26'	System	04 Apr 2021 19:00:29
	System	04 Apr 2021 19:00:29

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-04-09T19:39:10-07:00', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '332b5a09-95a8-4bdc-988c-bbed95834970'	System	10 Apr 2021 02:39:25
User entered 'No (N)'	System	10 Apr 2021 02:39:25

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-04-09T19:39:16-07:00', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '332b5a09-95a8-4bdc-988c-bbed95834970'	System	10 Apr 2021 02:39:25
User entered 'No (N)'	System	10 Apr 2021 02:39:25

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-04-09T19:39:22-07:00', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '332b5a09-95a8-4bdc-988c-bbed95834970'	System	10 Apr 2021 02:39:25
User entered '09 Apr 2021 19:39:22'	System	10 Apr 2021 02:39:25

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-04-16T02:00:41-07:00', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '49970623-2002-40f9-9be9-e1964bb58069'	System	16 Apr 2021 09:00:58
User entered 'No (N)'	System	16 Apr 2021 09:00:58

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-04-16T02:00:47-07:00', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '49970623-2002-40f9-9be9-e1964bb58069'	System	16 Apr 2021 09:00:58
User entered 'No (N)'	System	16 Apr 2021 09:00:58

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-04-16T02:00:54-07:00', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '49970623-2002-40f9-9be9-e1964bb58069'	System	16 Apr 2021 09:00:58
User entered '16 Apr 2021 02:00:54'	System	16 Apr 2021 09:00:58

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-04-23T15:29:07-07:00', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '6247046e-b4be-42d2-bea3-076e9ef14bab' User entered 'No (N)'	System	23 Apr 2021 22:29:18
	System	23 Apr 2021 22:29:18

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-04-23T15:29:11-07:00', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '6247046e-b4be-42d2-bea3-076e9ef14bab' User entered 'No (N)'	System	23 Apr 2021 22:29:18

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-04-23T15:29:14-07:00', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '6247046e-b4be-42d2-bea3-076e9ef14bab' User entered '23 Apr 2021 15:29:14'	System	23 Apr 2021 22:29:18
	System	23 Apr 2021 22:29:18

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-05-02T12:28:48-07:00', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '7a521816-5122-4f4a-a0d3-e5f862b8d4b7'	System	02 May 2021 19:29:04
User entered 'No (N)'	System	02 May 2021 19:29:04

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-05-02T12:28:52-07:00', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '7a521816-5122-4f4a-a0d3-e5f862b8d4b7'	System	02 May 2021 19:29:04
User entered 'No (N)'	System	02 May 2021 19:29:04

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-05-02T12:29:01-07:00', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '7a521816-5122-4f4a-a0d3-e5f862b8d4b7'	System	02 May 2021 19:29:04
User entered '02 May 2021 12:29:01'	System	02 May 2021 19:29:04

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 03:00:44

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:00:44
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 03:00:44

US3732262

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:22:21

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-03-01T08:28:58-08:00', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '731d33dd-bfeb-40c1-ba34-50a691a42048'	System	01 Mar 2021 16:29:08
User entered 'No (N)'	System	01 Mar 2021 16:29:08

US3732262

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:22:21

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2021-03-01T08:29:02-08:00', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '731d33dd-bfeb-40c1-ba34-50a691a42048' User entered '01 Mar 2021 08:29:02'	System	01 Mar 2021 16:29:08
	System	01 Mar 2021 16:29:08

US3732262

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:10
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:43:52
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:38:16
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
User entered 'Yes (Y)'	(b) (4) Sylvia Lindholm (b) (4)	02 Dec 2020 16:26:37

US3732262

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:10
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:43:52
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:38:16
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
User entered '02 Dec 2020'	(b) (4) Sylvia Lindholm (b) (4)	02 Dec 2020 16:26:37

US3732262

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:10
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:43:52
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:38:16
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sylvia Lindholm (b) (4)	02 Dec 2020 16:26:37

US3732262

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:10
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:43:52
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:38:16
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
User entered empty.	(b) (4) Sylvia Lindholm (b) (4)	02 Dec 2020 16:26:37

US3732262

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:10
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:43:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:38:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:58
User entered 'Yes (Y)'	(b) (4) Sylvia Lindholm (b) (4)	02 Dec 2020 16:26:41

US3732262

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:10
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 08:43:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:50:07
User entered 'l'	System	02 Dec 2020 16:26:41

US3732262

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:54
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:38:34
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
User entered 'Yes (Y)'	Linda Vega (b) (4)	08 Jan 2021 01:49:21

US3732262

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:54
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:38:34
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
User entered '07 Jan 2021'	Linda Vega (b) (4)	08 Jan 2021 01:49:21

US3732262

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:54
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:38:34
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Linda Vega (b) (4) (b) (4)	08 Jan 2021 01:49:21

US3732262

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:54
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:38:34
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
User entered empty.	Linda Vega (b) (4)	08 Jan 2021 01:49:21

US3732262

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:54
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:38:39
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
User entered 'Yes (Y)'	Linda Vega (b) (4)	08 Jan 2021 01:49:26

US3732262

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:54
User entered '1'	System	08 Jan 2021 01:49:26

US3732262

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:54
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:46:16
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 20:16:19

US3732262

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:54
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:46:16
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
User entered '04 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:16:19

US3732262

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:54
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:46:16
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:16:19

US3732262

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:54
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:46:16
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 20:16:19

US3732262

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:54
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:46:22
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 20:16:26

US3732262

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:54
User entered 'I'	System	09 Feb 2021 20:16:26

US3732262

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:59:48
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:46:46
User entered 'Yes (Y)'	Linda Vega (b) (4)	26 Feb 2021 21:31:35
	(b) (4)	

US3732262

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:59:48
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:46:46
User entered '26 Feb 2021'	Linda Vega (b) (4)	26 Feb 2021 21:31:35
	(b) (4)	

US3732262

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:59:48
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:46:46
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4)	26 Feb 2021 21:31:35
	(b) (4)	

US3732262

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:59:48
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:46:46
User entered empty.	Linda Vega (b) (4)	26 Feb 2021 21:31:35
	(b) (4)	

US3732262

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:59:48
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:46:55
User entered 'Yes (Y)'	Linda Vega (b) (4)	26 Feb 2021 21:31:42
	(b) (4)	

US3732262

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:59:48
User entered 'I'	System	26 Feb 2021 21:31:42

US3732262

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:22:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:50:18
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
User entered 'Yes (Y)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	01 Apr 2021 21:40:49

US3732262

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:50:18
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
User entered '30 Mar 2021'	(b) (4) Gordon Bovee (b) (4) (b) (4)	01 Apr 2021 21:40:49

US3732262

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:50:18
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
User entered 'Clinic (Clinic)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	01 Apr 2021 21:40:49

US3732262

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:22:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:31
User entered 'VISIT4'	System	01 Apr 2021 21:40:49

US3732262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:50:53
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
User entered 'Yes (Y)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	01 Apr 2021 21:42:06

US3732262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:50:53
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
User entered '30 Mar 2021'	(b) (4) Gordon Bovee (b) (4) (b) (4)	01 Apr 2021 21:42:06

US3732262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:50:53
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
User entered '13:41'	(b) (4) Gordon Bovee (b) (4) (b) (4)	01 Apr 2021 21:42:06

US3732262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:31
User entered '30 Mar 2021 13:41'	System	01 Apr 2021 21:42:06

US3732262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:50:53
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
User entered '98.2' F	(b) (4) Gordon Bovee (b) (4) (b) (4)	01 Apr 2021 21:42:06

US3732262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:50:53
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
User entered 'Oral (Oral)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	01 Apr 2021 21:42:06

US3732262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:50:53
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
User entered empty.	(b) (4) Gordon Bovee (b) (4) (b) (4)	01 Apr 2021 21:42:06

US3732262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:50:53
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
User entered '82'	(b) (4) Gordon Bovee (b) (4) (b) (4)	01 Apr 2021 21:42:06

US3732262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:31
User entered 'bpm'	System	01 Apr 2021 21:42:06

US3732262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:50:53
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
User entered '19'	(b) (4) Gordon Bovee (b) (4) (b) (4)	01 Apr 2021 21:42:06

US3732262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:31
User entered 'breaths/min'	System	01 Apr 2021 21:42:06

US3732262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:50:53
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
User entered '153'	(b) (4) Gordon Bovee (b) (4) (b) (4)	01 Apr 2021 21:42:06

US3732262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:31
User entered 'mmHg'	System	01 Apr 2021 21:42:06

US3732262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:50:53
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
User entered '97'	(b) (4) Gordon Bovee (b) (4) (b) (4)	01 Apr 2021 21:42:06

US3732262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:31
User entered 'mmHg'	System	01 Apr 2021 21:42:06

US3732262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:31

US3732262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:31

US3732262

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:22:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:50:30
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
User entered 'Yes (Y)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	01 Apr 2021 21:41:10

US3732262

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:22:21

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:50:30
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
User entered '30 Mar 2021'	(b) (4) Gordon Bovee (b) (4) (b) (4)	01 Apr 2021 21:41:10

US3732262

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:22:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:50:57
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
User entered 'Yes (Y)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	01 Apr 2021 21:42:24

US3732262

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:22:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:50:57
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
User entered '30 Mar 2021'	(b) (4) Gordon Bovee (b) (4) (b) (4)	01 Apr 2021 21:42:24

US3732262

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:22:21

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:50:57
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
User entered '13:53'	(b) (4) Gordon Bovee (b) (4) (b) (4)	01 Apr 2021 21:42:24

US3732262

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:22:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:31
User entered '30 Mar 2021 13:53'	System	01 Apr 2021 21:42:24

US3732262

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:10
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
User entered 'Yes (Y)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	01 Apr 2021 21:42:36

US3732262

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:31
User entered '1'	System	01 Apr 2021 21:42:36

US3732262

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	29 Apr 2021 21:19:55
	(b) (4)	
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	29 Apr 2021 00:19:13
	(b) (4)	

US3732262

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	29 Apr 2021 21:19:55
	(b) (4)	
User entered '27 Apr 2021'	Gordon Bovee (b) (4)	29 Apr 2021 00:19:13
	(b) (4)	

US3732262

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	29 Apr 2021 21:19:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Gordon Bovee (b) (4)	29 Apr 2021 00:19:13

US3732262

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	29 Apr 2021 21:19:55
User entered empty.	(b) (4) Gordon Bovee (b) (4)	29 Apr 2021 00:19:13
	(b) (4)	

US3732262

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	29 Apr 2021 21:19:55
	(b) (4)	
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	29 Apr 2021 00:19:29
	(b) (4)	

US3732262

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 00:19:29

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:22:21

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 23:00:11
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 20:30:29
User entered '10 Sep 2020' reason for change: Data Entry Error	Lauren Arnett (b) (4)	15 Sep 2020 18:39:23
User entered '08 Sep 2020' reason for change: Data Entry Error	Lauren Arnett (b) (4)	15 Sep 2020 18:31:53
User entered '10 Sep 2020' reason for change: Data Entry Error	Lauren Arnett (b) (4)	15 Sep 2020 18:29:50
User entered '14 Sep 2020'	Lauren Arnett (b) (4)	15 Sep 2020 18:28:27

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:22:21

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:00:11
User entered '14:01' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 20:30:29
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 18:40:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Sep 2020 18:40:36
User entered '12:00' reason for change: Data Entry Error	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:40:36
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 18:39:23
User entered empty; reason for change Data Entry Error	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:39:23
User entered '14:01' reason for change: Data Entry Error	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:31:53
User entered '16:25'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:28:27

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:22:21

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:32
User entered '08 Sep 2020 14:01'	System	24 Sep 2020 20:30:29
User entered '10 Sep 2020 12:00'	System	15 Sep 2020 18:40:36
User entered empty.	System	15 Sep 2020 18:39:23
User entered '08 Sep 2020 14:01'	System	15 Sep 2020 18:31:53
User entered '10 Sep 2020 16:25'	System	15 Sep 2020 18:29:50
User entered '14 Sep 2020 16:25'	System	15 Sep 2020 18:28:27

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:22:21

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:32
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 19:08:42
User closed query 'Per eCRF Completion Guidelines (P.59) please select "Safety Call" from the Drop Down Menu.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:08:40
Query 'Per eCRF Completion Guidelines (P.59) please select "Safety Call" from the Drop Down Menu.' answered by data change (Site from CRA).	System	01 Apr 2021 21:36:13
Signature has been broken.	Gordon Bovee (b) (4)	01 Apr 2021 21:36:13
	(b) (4)	
User entered 'Safety Call (Safety Call)' reason for change: Per Query Resolution	Gordon Bovee (b) (4)	01 Apr 2021 21:36:13
	(b) (4)	
User opened query 'Per eCRF Completion Guidelines (P.59) please select "Safety Call" from the Drop Down Menu.' (Site from CRA).	(b) (4), (b) (6)	25 Mar 2021 21:59:11
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 21:58:16
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 23:00:11
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Lauren Arnett (b) (4)	15 Sep 2020 18:28:27
	(b) (4)	

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:22:21

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:32
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:00:11
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:28:27

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:22:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 17:11:50
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	23 Mar 2021 16:52:02
User entered 'Day 3 (Day 3)'	Lauren Arnett (b) (4)	15 Sep 2020 18:40:48
	(b) (4)	
	Lauren Arnett (b) (4)	15 Sep 2020 18:35:38
	(b) (4)	

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:22:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:02:36
User entered '10 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 16:52:50
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:52:02
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:40:48
User entered '12 Sep 2020'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:35:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:22:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:02:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:52:02
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	15 Sep 2020 18:40:48
User entered '0'	(b) (4) Lauren Arnett (b) (4)	15 Sep 2020 18:35:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:22:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:02:53
User entered '98' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 16:52:50
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:52:02
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:40:48
User entered '99'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:35:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:22:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:52:02
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	15 Sep 2020 18:40:48
User entered '%'	(b) (4) System	15 Sep 2020 18:35:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:22:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:02:56
User entered '100.0' F reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 16:52:50
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:52:02
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	15 Sep 2020 18:40:48
User entered '98.8' F	(b) (4) Lauren Arnett (b) (4)	15 Sep 2020 18:35:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:22:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:03:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:52:02
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	15 Sep 2020 18:40:48
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:35:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:22:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:03:55
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:52:02
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	15 Sep 2020 18:40:48
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:35:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:22:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:03:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:52:02
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	15 Sep 2020 18:40:48
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4)	15 Sep 2020 18:35:38
	(b) (4)	

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:22:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:03:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:52:02
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	15 Sep 2020 18:40:48
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4)	15 Sep 2020 18:35:38
	(b) (4)	

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:22:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:03:59
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:52:02
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	15 Sep 2020 18:40:48
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:35:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:22:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:04:00
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:52:02
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	15 Sep 2020 18:40:48
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:35:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:22:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:04:02
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:52:02
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	15 Sep 2020 18:40:48
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4)	15 Sep 2020 18:35:38
	(b) (4)	

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:22:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:04:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:52:02
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	15 Sep 2020 18:40:48
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:35:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:22:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:04:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:52:02
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	15 Sep 2020 18:40:48
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:35:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:22:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:04:08
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:52:02
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	15 Sep 2020 18:40:48
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:35:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:22:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:04:09
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:52:02
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	15 Sep 2020 18:40:48
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:35:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:22:21

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:04:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:52:02
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	15 Sep 2020 18:40:48
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4)	15 Sep 2020 18:35:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:22:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:04:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:52:02
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	15 Sep 2020 18:40:48
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4)	15 Sep 2020 18:35:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:22:21

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:04:15
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:52:02
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	15 Sep 2020 18:40:48
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:35:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:22:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:04:17
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:52:02
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	15 Sep 2020 18:40:48
User entered 'None (None)'	(b) (4) Lauren Arnett (b) (4)	15 Sep 2020 18:35:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:22:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:04:19
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:52:02
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	15 Sep 2020 18:40:48
User entered 'Mild (Mild)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:35:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:22:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 17:11:50
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 17:11:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
User entered 'Day 2 (Day 2)'	(b) (4)	
	Lauren Arnett (b) (4)	15 Sep 2020 18:43:04
	(b) (4)	

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:22:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '11 Sep 2020'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:43:04

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:22:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '0'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:43:04

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:22:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '98'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:43:04

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:22:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User entered '%'	System	15 Sep 2020 18:43:04

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:22:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '98.8' F	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:43:04

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:22:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4)	15 Sep 2020 18:43:04
	(b) (4)	

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:22:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:43:04

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:22:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:43:04

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:22:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:43:04

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:22:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4)	15 Sep 2020 18:43:04
	(b) (4)	

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:22:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:43:04

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:22:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4)	15 Sep 2020 18:43:04
	(b) (4)	

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:22:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:43:04

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:22:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:43:04

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:22:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:43:04

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:22:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:43:04

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:22:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4)	15 Sep 2020 18:43:04
	(b) (4)	

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:22:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:43:04

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:22:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:43:04

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:22:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4)	15 Sep 2020 18:43:04
	(b) (4)	

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:22:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'Mild (Mild)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:43:04

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:22:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
Signature has been broken.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:11:50
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 17:11:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
User entered 'Day 3 (Day 3)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:44:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:22:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '12 Sep 2020'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:44:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:22:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '0'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:44:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:22:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '99'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:44:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:22:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User entered '%'	System	15 Sep 2020 18:44:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:22:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '98.8' F	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:44:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:22:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4)	15 Sep 2020 18:44:25
	(b) (4)	

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:22:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:44:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:22:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:44:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:22:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:44:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:22:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:44:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:22:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:44:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:22:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:44:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:22:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:44:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:22:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:44:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:22:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:44:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:22:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:44:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:22:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:44:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:22:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:44:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:22:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:44:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:22:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:44:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:22:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'Mild (Mild)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:44:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:22:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 17:11:50
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 17:11:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
	(b) (4)	
User entered 'Day 4 (Day 4)'	Lauren Arnett (b) (4)	15 Sep 2020 18:46:16
	(b) (4)	

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:22:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '13 Sep 2020'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:46:16

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:22:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '0'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:46:16

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:22:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '99'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:46:16

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:22:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User entered '%'	System	15 Sep 2020 18:46:16

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:22:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '99.0' F	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:46:16

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:22:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4)	15 Sep 2020 18:46:16
	(b) (4)	

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:22:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4)	15 Sep 2020 18:46:16
	(b) (4)	

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:22:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:46:16

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:22:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:46:16

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:22:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:46:16

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:22:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:46:16

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:22:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:46:16

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:22:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:46:16

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:22:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:46:16

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:22:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:46:16

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:22:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:46:16

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:22:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:46:16

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:22:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:46:16

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:22:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4)	15 Sep 2020 18:46:16
	(b) (4)	

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:22:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4)	15 Sep 2020 18:46:16
	(b) (4)	

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:22:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'Mild (Mild)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:46:16

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:22:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 17:11:50
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 17:11:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
	(b) (4)	
User entered 'Day 5 (Day 5)'	Lauren Arnett (b) (4)	15 Sep 2020 18:47:24
	(b) (4)	

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:22:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '14 Sep 2020'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:47:24

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:22:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '0'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:47:24

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:22:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '99'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:47:24

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:22:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User entered '%'	System	15 Sep 2020 18:47:24

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:22:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '99.1' F	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:47:24

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:22:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:47:24

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:22:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4)	15 Sep 2020 18:47:24
	(b) (4)	

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:22:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:47:24

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:22:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:47:24

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:22:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4)	15 Sep 2020 18:47:24
	(b) (4)	

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:22:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:47:24

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:22:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:47:24

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:22:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:47:24

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:22:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:47:24

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:22:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:47:24

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:22:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:47:24

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:22:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:47:24

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:22:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:47:24

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:22:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:47:24

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:22:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:47:24

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:22:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'Mild (Mild)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 18:47:24

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:22:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 17:11:50
User entered 'Day 10 (Day 10)' reason for change:	(b) (4), (b) (6)	23 Mar 2021 17:11:50
Data Entry Error		
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
	(b) (4)	
User entered 'Day 6 (Day 6)'	(b) (4), (b) (6)	22 Sep 2020 23:29:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:22:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '15 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 23:29:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:22:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	23 Oct 2020 23:12:58
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 23:29:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:22:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '98' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 23:38:14
User entered '97' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 23:29:46
User entered '97.' (non-conformant).	(b) (4), (b) (6)	22 Sep 2020 23:29:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:22:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User entered '%'	System	22 Sep 2020 23:29:46
User entered empty.	System	22 Sep 2020 23:29:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:22:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '97.6' F	(b) (4), (b) (6)	22 Sep 2020 23:29:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:22:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	22 Sep 2020 23:29:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:22:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	22 Sep 2020 23:29:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:22:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	22 Sep 2020 23:29:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:22:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	22 Sep 2020 23:29:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:22:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	22 Sep 2020 23:29:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:22:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	22 Sep 2020 23:29:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:22:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	22 Sep 2020 23:29:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:22:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	22 Sep 2020 23:29:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:22:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	22 Sep 2020 23:29:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:22:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	22 Sep 2020 23:29:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:22:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	22 Sep 2020 23:29:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:22:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	22 Sep 2020 23:29:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:22:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	22 Sep 2020 23:29:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:22:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	22 Sep 2020 23:29:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:22:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	22 Sep 2020 23:29:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:22:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Sep 2020 23:29:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:22:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
Signature has been broken.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:11:50
User entered 'Day 11 (Day 11)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 17:11:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Sep 2020 23:37:50
User entered empty.		22 Sep 2020 23:29:46

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:22:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	23 Oct 2020 23:12:58
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 23:37:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Sep 2020 23:37:38
User entered '16 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 23:37:38
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 23:29:46
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 23:29:46

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:22:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 23:29:46

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:22:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '99' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 23:37:38
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 23:29:46

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:22:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User entered '%'	System	22 Sep 2020 23:37:38
User entered empty.	System	22 Sep 2020 23:29:46

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:22:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '97.6' F reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 23:37:38
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 23:29:46

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:22:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 23:37:38
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 23:29:46

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:22:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 23:37:38
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 23:29:46

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:22:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 23:37:38
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 23:29:46

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:22:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 23:37:38
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 23:29:46

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:22:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 23:37:38
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 23:29:46

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:22:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 23:37:38
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 23:29:46

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:22:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 23:37:38
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 23:29:46

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:22:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 23:37:38
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 23:29:46

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:22:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 23:37:38
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 23:29:46

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:22:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 23:37:38
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 23:29:46

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:22:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 23:37:38
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 23:29:46

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:22:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 23:37:38
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 23:29:46

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:22:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 23:37:38
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 23:29:46

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:22:21

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 23:37:38
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 23:29:46

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:22:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 23:37:38
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 23:29:46

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:22:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 23:37:38
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 23:29:46

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:22:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
Signature has been broken.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:11:50
User entered 'Day 12 (Day 12)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 17:11:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
User entered 'Day 8 (Day 8)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 01:07:23

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:22:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '17 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 01:07:23

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:22:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	23 Oct 2020 23:12:58
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 01:07:23

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:22:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '100'	(b) (4), (b) (6)	23 Sep 2020 01:07:23

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:22:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User entered '%'	System	23 Sep 2020 01:07:23

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:22:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 22:12:25
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
User closed query 'Per CDM: please review value as it seems rather high' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:23:56
Query 'Per CDM: please review value as it seems rather high' answered with 'entry error' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 22:53:56
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 22:53:51
User entered '97.7' F reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 22:53:51
User opened query 'Per CDM: please review value as it seems rather high' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 16:12:55
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '97.7' C	(b) (4), (b) (6)	23 Sep 2020 01:07:23

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:22:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:07:23

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:22:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:07:23

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:22:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:07:23

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:22:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:07:23

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:22:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:07:23

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:22:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:07:23

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:22:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:07:23

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:22:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	23 Oct 2020 23:12:58
User entered 'Mild (Mild)'	(b) (4), (b) (6)	23 Sep 2020 01:07:23

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:22:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:07:23

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:22:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:07:23

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:22:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:07:23

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:22:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:07:23

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:22:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:07:23

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:22:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:07:23

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:22:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:07:23

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:22:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'Mild (Mild)'	(b) (4), (b) (6)	23 Sep 2020 01:07:23

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:22:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
Signature has been broken.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:11:50
User entered 'Day 13 (Day 13)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 17:11:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
User entered 'Day 9 (Day 9)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 01:13:56

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:22:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '18 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 01:13:56

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:22:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 01:13:56

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:22:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '100'	(b) (4), (b) (6)	23 Sep 2020 01:13:56

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:22:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User entered '%'	System	23 Sep 2020 01:13:56

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:22:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	25 Mar 2021 22:13:48
DataPoint Un-verified.	(b) (4), (b) (6)	23 Mar 2021 17:17:22
Signature has been broken.	(b) (4), (b) (6)	23 Mar 2021 17:17:22
User entered '99.1' F reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 17:17:22
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	23 Oct 2020 23:12:58
User entered '99.7' F	(b) (4), (b) (6)	23 Sep 2020 01:13:56

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:22:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:13:56

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:22:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:13:56

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:22:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:13:56

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:22:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:13:56

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:22:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:13:56

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:22:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:13:56

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:22:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:13:56

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:22:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:13:56

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:22:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:13:56

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:22:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:13:56

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:22:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:13:56

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:22:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:13:56

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:22:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:13:56

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:22:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:13:56

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:22:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:13:56

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:22:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'Mild (Mild)'	(b) (4), (b) (6)	23 Sep 2020 01:13:56

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:22:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
Signature has been broken.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:11:50
User entered 'Day 14 (Day 14)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 17:11:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
User entered 'Day 10 (Day 10)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 01:15:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:22:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '19 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 01:15:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:22:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 01:15:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:22:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '99'	(b) (4), (b) (6)	23 Sep 2020 01:15:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:22:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User entered '%'	System	23 Sep 2020 01:15:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:22:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 22:16:11
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
User closed query 'Per CDM: please review value as it seems rather high' (Site from DM).	(b) (4)	
Query 'Per CDM: please review value as it seems rather high' answered with 'entry error' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:24:16
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 22:54:28
User entered '98.4' F reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 22:54:19
User opened query 'Per CDM: please review value as it seems rather high' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 16:13:10
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '98.4' C	(b) (4), (b) (6)	23 Sep 2020 01:15:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:22:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:15:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:22:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:15:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:22:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:15:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:22:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:15:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:22:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:15:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:22:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:15:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:22:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:15:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:22:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:15:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:22:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:15:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:22:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:15:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:22:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:15:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:22:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:15:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:22:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:15:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:22:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:15:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:22:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:15:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:22:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:15:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:22:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
User closed query 'Per CDM: Per sponsor review, please verify data and add entry for Symptom Day 11 (20Sep2020) to Symptom Log. ' (Site from DM).	(b) (4)	25 Mar 2021 06:19:55
Query 'Per CDM: Per sponsor review, please verify data and add entry for Symptom Day 11 (20Sep2020) to Symptom Log. ' answered with 'Symptom log has been updated.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 17:18:17
Signature has been broken.	(b) (4), (b) (6)	23 Mar 2021 17:11:50
User entered 'Day 16 (Day 16)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 17:11:50
User opened query 'Per CDM: Per sponsor review, please verify data and add entry for Symptom Day 11 (20Sep2020) to Symptom Log. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 13:18:34
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
User entered 'Day 12 (Day 12)'	(b) (4), (b) (6)	23 Sep 2020 01:16:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:22:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '21 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 01:16:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:22:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 01:16:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:22:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:49:04
User closed query 'Per Source; "O2 Saturation = 99%". Please update data point.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 22:48:57
Query 'Per Source; "O2 Saturation = 99%". Please update data point.' answered with 'updated per source' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 19:16:29
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 19:16:20
User entered '99' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 19:16:20
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User opened query 'Per Source; "O2 Saturation = 99%". Please update data point.' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 23:10:31
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 01:16:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:22:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User entered '%'	System	05 Nov 2020 19:16:20
User entered empty.	System	23 Sep 2020 01:16:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:22:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	06 Nov 2020 22:49:05
User closed query 'Per Source, " Temperature = 97.5 F". Please update data point.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 22:49:01
Query 'Per Source, " Temperature = 97.5 F". Please update data point.' answered with 'updated per source' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 19:16:41
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 19:16:20
User entered '97.5' F reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 19:16:20
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User opened query 'Per Source, " Temperature = 97.5 F". Please update data point.' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 23:11:04
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 01:16:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:22:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:16:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:22:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:16:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:22:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:16:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:22:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:16:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:22:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 01:17:25
User entered 'Mild (Mild)'	(b) (4), (b) (6)	23 Sep 2020 01:16:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:22:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:16:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:22:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:16:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:22:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:16:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:22:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:16:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:22:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:16:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:22:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:16:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:22:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:16:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:22:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 01:17:25
User entered 'Mild (Mild)'	(b) (4), (b) (6)	23 Sep 2020 01:16:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:22:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:16:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:22:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:16:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:22:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:16:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:22:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
Signature has been broken.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:11:50
User entered 'Day 17 (Day 17)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 17:11:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
User entered 'Day 13 (Day 13)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 01:17:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:22:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	23 Oct 2020 23:12:58
User entered '22 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 01:17:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:22:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 01:17:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:22:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '99'	(b) (4), (b) (6)	23 Sep 2020 01:17:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:22:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User entered '%'	System	23 Sep 2020 01:17:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:22:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '97.2' F	(b) (4), (b) (6)	23 Sep 2020 01:17:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:22:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:17:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:22:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:17:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:22:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:17:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:22:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:17:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:22:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:17:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:22:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:17:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:22:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:17:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:22:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:17:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:22:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:17:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:22:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:17:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:22:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:17:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:22:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:17:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:22:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:17:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:22:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:17:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:22:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:17:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:22:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 01:17:25

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:22:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 17:11:50
User entered 'Day 18 (Day 18)' reason for change:	(b) (4), (b) (6)	23 Mar 2021 17:11:50
Data Entry Error		
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
	(b) (4)	
User entered 'Day 14 (Day 14)'	(b) (4), (b) (6)	30 Sep 2020 19:57:45

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:22:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '23 Sep 2020'	(b) (4), (b) (6)	30 Sep 2020 19:57:45

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:22:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 19:57:45

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:22:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '99'	(b) (4), (b) (6)	30 Sep 2020 19:57:45

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:22:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User entered '%'	System	30 Sep 2020 19:57:45

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:22:21

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '97.7' F	(b) (4), (b) (6)	30 Sep 2020 19:57:45

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:22:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 19:57:45

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:22:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 19:57:45

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:22:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 19:57:45

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:22:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 19:57:45

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:22:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 19:57:45

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:22:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 19:57:45

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:22:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 19:57:45

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:22:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 19:57:45

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:22:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 19:57:45

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:22:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 19:57:45

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:22:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 19:57:45

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:22:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 19:57:45

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:22:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 19:57:45

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:22:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 19:57:45

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:22:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 19:57:45

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:22:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 19:57:45

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:22:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
User closed query 'Per CDM: Per sponsor review, please add entries for Symptom Days 15-20 to Symptom Log. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 06:18:38
Query 'Per CDM: Per sponsor review, please add entries for Symptom Days 15-20 to Symptom Log. ' answered with 'Symptom log has been updated. Subject was asymptomatic from Illness Visit Day 10 onwards, therefore Telemedicine Convalescent Visits only occurred on Days 1-14, Day 21 & Day 28.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 17:29:18
Signature has been broken.	(b) (4), (b) (6)	23 Mar 2021 17:11:50
User entered 'Day 25 (Day 25)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 17:11:50
User opened query 'Per CDM: Per sponsor review, please add entries for Symptom Days 15-20 to Symptom Log. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 13:19:29
Data hard unlocked.	(b) (4), (b) (6)	17 Mar 2021 13:18:52
Data hard locked.	(b) (4), (b) (6)	17 Mar 2021 13:18:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
User entered 'Day 21 (Day 21)'	(b) (4), (b) (6)	30 Sep 2020 20:01:33

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:22:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '30 Sep 2020'	(b) (4), (b) (6)	30 Sep 2020 20:01:33

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:22:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 20:01:33

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:22:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '99'	(b) (4), (b) (6)	30 Sep 2020 20:01:33

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:22:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User entered '%'	System	30 Sep 2020 20:01:33

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:22:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '99.1' F	(b) (4), (b) (6)	30 Sep 2020 20:01:33

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:22:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 20:01:33

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:22:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 20:01:33

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:22:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 20:01:33

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:22:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 20:01:33

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:22:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 20:01:33

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:22:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 20:01:33

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:22:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 20:01:33

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:22:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 20:01:33

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:22:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 20:01:33

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:22:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 20:01:33

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:22:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 20:01:33

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:22:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 20:01:33

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:22:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 20:01:33

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:22:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 20:01:33

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:22:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 20:01:33

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:22:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 20:01:33

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:22:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
Signature has been broken.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:11:50
User entered 'Day 32 (Day 32)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 17:11:50
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
User entered 'Day 1 (Day 1)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:16:04

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:22:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:25:37
DataPoint Un-verified.	(b) (4), (b) (6)	23 Mar 2021 17:04:55
Signature has been broken.	(b) (4), (b) (6)	23 Mar 2021 17:04:55
User entered '07 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 17:04:55
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
User closed query 'Per CDM; Please reconcile Day 1 date as it appears to be after Contact date of 08SEP2020' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 20:10:21
Query 'Per CDM; Please reconcile Day 1 date as it appears to be after Contact date of 08SEP2020' answered with 'data entered is correct as is, please note that subject was positive at baseline visit, site received +PCR results and contacted subject on 9/8, subject returned to site for day 1 illness visit om 9/10' (Site from DM).	Lauren Arnett (b) (4) (b) (4)	09 Nov 2020 17:05:38
User opened query 'Per CDM; Please reconcile Day 1 date as it appears to be after Contact date of 08SEP2020' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 06:03:05
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '10 Sep 2020'	(b) (4), (b) (6)	07 Oct 2020 20:16:04

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:22:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 20:16:04

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:22:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	25 Mar 2021 22:25:39
DataPoint Un-verified.	(b) (4), (b) (6)	23 Mar 2021 17:04:55
Signature has been broken.	(b) (4), (b) (6)	23 Mar 2021 17:04:55
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 17:04:55
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	23 Oct 2020 23:12:58
User entered '98'	(b) (4), (b) (6)	07 Oct 2020 20:16:04

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:22:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User entered '%'	System	07 Oct 2020 20:16:04

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:22:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	25 Mar 2021 22:25:46
DataPoint Un-verified.	(b) (4), (b) (6)	23 Mar 2021 17:04:55
Signature has been broken.	(b) (4), (b) (6)	23 Mar 2021 17:04:55
User entered '98.6' F reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 17:04:55
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	23 Oct 2020 23:12:58
User entered '100.0' F	(b) (4), (b) (6)	07 Oct 2020 20:16:04

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:22:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	07 Oct 2020 20:16:04

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:22:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	07 Oct 2020 20:16:04

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:22:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	07 Oct 2020 20:16:04

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:22:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	07 Oct 2020 20:16:04

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:22:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	07 Oct 2020 20:16:04

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:22:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	07 Oct 2020 20:16:04

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:22:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	07 Oct 2020 20:16:04

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:22:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	07 Oct 2020 20:16:04

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:22:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	07 Oct 2020 20:16:04

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:22:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	07 Oct 2020 20:16:04

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:22:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	07 Oct 2020 20:16:04

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:22:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	07 Oct 2020 20:16:04

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:22:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	07 Oct 2020 20:16:04

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:22:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	07 Oct 2020 20:16:04

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:22:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:12:58
User entered 'None (None)'	(b) (4), (b) (6)	07 Oct 2020 20:16:04

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:22:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	25 Mar 2021 22:25:51
DataPoint Un-verified.	(b) (4), (b) (6)	23 Mar 2021 17:04:55
Signature has been broken.	(b) (4), (b) (6)	23 Mar 2021 17:04:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 17:04:55
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	23 Oct 2020 23:12:58
User entered 'Mild (Mild)'	(b) (4), (b) (6)	07 Oct 2020 20:16:04

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:22:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
User entered 'Day 15 (Day 15)' reason for change: Data Entry Error	(b) (4)	23 Mar 2021 17:11:50
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:53:56
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	09 Nov 2020 18:23:24
User entered 'Day 11 (Day 11)'	(b) (4)	27 Oct 2020 17:20:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:22:21

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	25 Mar 2021 22:29:27
User closed query 'Please inactivate this line only if not completed' (Site from CRA).	(b) (4), (b) (6)	25 Mar 2021 22:28:48
User closed query 'Per CDM: It appears there may be additional records missing as a Convalescence Visit Day 28 is recorded with a date of 07OCT2020. Please reconcile or clarify' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 06:18:58
User entered '20 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 16:54:08
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:53:56
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	09 Nov 2020 18:23:24
Query 'Please inactivate this line only if not completed' answered with 'please note day 11 not complete due to symptoms resolving, log line to be inactivated' (Site from CRA).	Lauren Arnett (b) (4)	09 Nov 2020 18:23:10
Query 'Per CDM: It appears there may be additional records missing as a Convalescence Visit Day 28 is recorded with a date of 07OCT2020. Please reconcile or clarify' answered with 'symptom log updated' (Site from DM).	Lauren Arnett (b) (4)	09 Nov 2020 18:22:47
User opened query 'Per CDM: It appears there may be additional records missing as a Convalescence Visit Day 28 is recorded with a date of 07OCT2020. Please reconcile or clarify' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 06:02:18
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 06:01:55
User opened query 'Please inactivate this line only if not completed' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 19:34:32
User closed query 'Per Source, This Date is "N/A". Can You delete or line out information on this page? Was eCRF completed in error?' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 19:34:32
Query 'Data is required. Please complete.' answered with 'deleted per CRA request- since Day 11 was not completed ' (Site from System).	(b) (4), (b) (6)	07 Nov 2020 00:01:26

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:22:21

[Date](#)

Audit	User	Time (GMT)
Query 'Per Source, This Date is "N/A". Can You delete or line out information on this page? Was eCRF completed in error?' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 00:01:01
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Nov 2020 00:00:47
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 00:00:47
User opened query 'Per Source, This Date is "N/A". Can You delete or line out information on this page? Was eCRF completed in error?' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 22:51:24
User entered '20 Sep 2020'	(b) (4), (b) (6)	27 Oct 2020 17:20:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:22:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	25 Mar 2021 22:29:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:53:56
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	09 Nov 2020 18:23:24
User entered 'I'	(b) (4), (b) (6)	27 Oct 2020 17:20:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:22:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:29:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:53:56
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	09 Nov 2020 18:23:24
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 17:20:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:22:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:53:56
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	09 Nov 2020 18:23:24
User entered empty.	(b) (4) System	27 Oct 2020 17:20:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:22:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:29:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:53:56
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	09 Nov 2020 18:23:24
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:20:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:22:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:29:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:53:56
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	09 Nov 2020 18:23:24
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 17:20:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:22:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:29:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:53:56
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	09 Nov 2020 18:23:24
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:20:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:22:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:29:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:53:56
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	09 Nov 2020 18:23:24
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 17:20:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:22:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:29:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:53:56
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	09 Nov 2020 18:23:24
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:20:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:22:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:29:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:53:56
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	09 Nov 2020 18:23:24
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:20:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:22:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:29:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:53:56
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	09 Nov 2020 18:23:24
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:20:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:22:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:29:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:53:56
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	09 Nov 2020 18:23:24
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 17:20:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:22:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:29:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:53:56
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	09 Nov 2020 18:23:24
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:20:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:22:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:29:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:53:56
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	09 Nov 2020 18:23:24
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:20:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:22:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	25 Mar 2021 22:29:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:53:56
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	09 Nov 2020 18:23:24
User entered empty.	(b) (4)	27 Oct 2020 17:20:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:22:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:29:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:53:56
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	09 Nov 2020 18:23:24
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 17:20:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:22:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:29:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:53:56
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	09 Nov 2020 18:23:24
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:20:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:22:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:29:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:53:56
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	09 Nov 2020 18:23:24
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 17:20:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:22:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:29:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:53:56
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	09 Nov 2020 18:23:24
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 17:20:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:22:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:29:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:53:56
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	09 Nov 2020 18:23:24
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:20:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:22:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:29:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 16:53:56
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	09 Nov 2020 18:23:24
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:20:38

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:22:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
User entered 'Day 1 (Day 1)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:08:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 17:05:39
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4) (b) (4)	18 Nov 2020 22:17:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:22:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:59:46
User entered '06 Sep 2020'	(b) (4), (b) (6)	23 Mar 2021 17:08:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 17:05:39
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4) (b) (4)	18 Nov 2020 22:17:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:22:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:59:48
User entered '0'	(b) (4), (b) (6)	23 Mar 2021 17:08:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 17:05:39
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4) (b) (4)	18 Nov 2020 22:17:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:22:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:59:50
User entered missing code ND - Not Done.	(b) (4), (b) (6)	23 Mar 2021 17:08:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 17:05:39
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4) (b) (4)	18 Nov 2020 22:17:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:22:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User entered '%'	System	23 Mar 2021 17:08:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 17:05:39
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	18 Nov 2020 22:17:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:22:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:59:52
User entered missing code ND - Not Done.	(b) (4), (b) (6)	23 Mar 2021 17:08:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 17:05:39
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4) (b) (4)	18 Nov 2020 22:17:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:22:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:59:53
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 17:05:39
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4) (b) (4)	18 Nov 2020 22:17:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:22:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:59:55
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 17:05:39
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4) (b) (4)	18 Nov 2020 22:17:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:22:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:59:56
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 17:05:39
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4) (b) (4)	18 Nov 2020 22:17:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:22:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:59:58
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 17:05:39
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4) (b) (4)	18 Nov 2020 22:17:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:22:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:59:59
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 17:05:39
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4) (b) (4)	18 Nov 2020 22:17:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:22:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:00:01
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 17:05:39
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4) (b) (4)	18 Nov 2020 22:17:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:22:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:00:03
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 17:05:39
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4) (b) (4)	18 Nov 2020 22:17:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:22:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:00:05
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 17:05:39
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4) (b) (4)	18 Nov 2020 22:17:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:22:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:00:06
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 17:05:39
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4) (b) (4)	18 Nov 2020 22:17:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:22:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:00:08
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 17:05:39
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4) (b) (4)	18 Nov 2020 22:17:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:22:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:00:09
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 17:05:39
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4) (b) (4)	18 Nov 2020 22:17:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:22:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:00:10
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 17:05:39
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4) (b) (4)	18 Nov 2020 22:17:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:22:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:00:12
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 17:05:39
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4) (b) (4)	18 Nov 2020 22:17:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:22:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:00:13
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 17:05:39
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4) (b) (4)	18 Nov 2020 22:17:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:22:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:00:15
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 17:05:39
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4) (b) (4)	18 Nov 2020 22:17:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:22:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:59:42
User entered 'Mild (Mild)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Mar 2021 17:05:39
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4) (b) (4)	18 Nov 2020 22:17:05

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:22:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
User entered 'Day 2 (Day 2)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:22:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:00:21
User entered '07 Sep 2020'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:22:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:00:24
User entered '0'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:22:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:00:28
User entered missing code ND - Not Done.	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:22:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User entered '%'	System	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:22:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:00:29
User entered missing code ND - Not Done.	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:22:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:00:31
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:22:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:00:32
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:22:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:00:34
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:22:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:00:36
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:22:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:00:37
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:22:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:00:39
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:22:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:00:40
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:22:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:00:42
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:22:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:00:43
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:22:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:00:45
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:22:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:00:46
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:22:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:00:48
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:22:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:00:49
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:22:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:00:51
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:22:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:00:52
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:22:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:00:54
User entered 'Mild (Mild)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:22:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
User entered 'Day 3 (Day 3)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:22:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:01:00
User entered '08 Sep 2020'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:22:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:01:02
User entered '0'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:22:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:01:03
User entered missing code ND - Not Done.	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:22:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User entered '%'	System	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:22:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:01:05
User entered missing code ND - Not Done.	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:22:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:01:06
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:22:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:01:08
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:22:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:01:09
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:22:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:01:10
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:22:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:01:12
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:22:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:01:13
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:22:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:01:15
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:22:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:01:16
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:22:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:01:18
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:22:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:01:20
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:22:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:01:21
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:22:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:01:23
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:22:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:01:25
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:22:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:01:26
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:22:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:01:27
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:22:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:01:29
User entered 'Mild (Mild)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:22:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
User entered 'Day 4 (Day 4)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:22:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:01:35
User entered '09 Sep 2020'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:22:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:01:37
User entered '0'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:22:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:01:38
User entered missing code ND - Not Done.	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:22:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User entered '%'	System	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:22:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:01:40
User entered missing code ND - Not Done.	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:22:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:01:41
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:22:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:01:42
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:22:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:01:44
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:22:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:01:45
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:22:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:01:46
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:22:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:01:48
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:22:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:01:49
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:22:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:01:50
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:22:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:01:52
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:22:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:22:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:01:54
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:22:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:01:56
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:22:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:01:57
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:22:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:01:59
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:22:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:02:01
User entered 'None (None)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:22:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:46:41
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:02:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	23 Mar 2021 17:08:51

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:22:21

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:16
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:13:42
User entered '10 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 23:27:45

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:22:21

[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 19:47:16
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:13:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 23:27:45

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:22:21

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 19:47:16
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	06 Nov 2020 04:05:13
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'previously updated' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 19:09:26
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 23:13:42
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	22 Sep 2020 23:27:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 23:27:45

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:22:21

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:16
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:13:42
User entered '10 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 23:27:45

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:22:21

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:16
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:13:42
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	22 Sep 2020 23:27:45

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:22:21

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:16
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:13:42
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 23:27:45

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:22:21

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:16
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:13:42
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 23:27:45

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:22:21

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:16
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:13:42
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 23:27:45

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:22:21

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:16
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:13:42
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 23:27:45

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:22:21

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:16
User entered 'I'	System	22 Sep 2020 23:27:45

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 00:37:39
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
User closed query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia sections of this form and provide responses.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 12:21:35
Query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia sections of this form and provide responses.' answered with 'Updated.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 17:49:01
User opened query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia sections of this form and provide responses.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 04:47:55
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 00:37:39
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:29:55
DataPoint Un-verified.	(b) (4), (b) (6)	23 Mar 2021 17:48:20
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 17:48:20
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:29:55
DataPoint Un-verified.	(b) (4), (b) (6)	23 Mar 2021 17:48:20
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 17:48:20
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:29:55
DataPoint Un-verified.	(b) (4), (b) (6)	23 Mar 2021 17:48:20
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 17:48:20
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:29:55
DataPoint Un-verified.	(b) (4), (b) (6)	23 Mar 2021 17:48:20
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 17:48:20
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 00:37:39
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 22:29:55
DataPoint Un-verified.	(b) (4), (b) (6)	23 Mar 2021 17:47:46
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 17:47:46
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:14:24
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 20:17:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 20:17:34
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 20:17:34
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 20:17:22
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:22:21

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:47:43
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:14:24
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:17:22

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 12 Aug 2021 13:22:21

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:48:21
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:24:05
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	09 Nov 2020 18:23:58

US3732262

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:22:21

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:48
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	23 Sep 2020 01:04:29

US3732262

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:22:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:48
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:53:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 01:04:29

US3732262

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:22:21

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:48
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:53:45
User entered '12 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 01:04:29

US3732262

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:22:21

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:48
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	23 Sep 2020 01:04:29

US3732262

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:22:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:48
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:58:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 01:04:29

US3732262

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:22:21

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:48
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:58:12
User entered '14 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 01:04:29

US3732262

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:22:21

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:48
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	23 Sep 2020 01:04:29

US3732262

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:22:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:48
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:58:12
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 22:04:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 22:04:06
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 22:04:06
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 01:04:29
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 01:04:29

US3732262

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:22:21

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:48
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:12
User entered '16 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 22:04:06
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 01:04:29

US3732262

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:22:21

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:48
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	23 Sep 2020 01:04:29

US3732262

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:22:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:48
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:58:12
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 22:05:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 22:05:53
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 22:05:53
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 01:04:29
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 01:04:29

US3732262

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:22:21

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:48
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:12
User entered '18 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 22:05:53
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 01:04:29

US3732262

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:22:21

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:48
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	23 Sep 2020 01:04:29

US3732262

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:22:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:48
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:58:12
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 22:05:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 22:05:53
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 22:05:53
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 01:04:29
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 01:04:29

US3732262

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:22:21

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:48
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:12
User entered '23 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 22:05:53
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 01:04:29

US3732262

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:22:21

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:48
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	23 Sep 2020 01:04:29

US3732262

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:22:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:48
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:58:12
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 22:05:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 22:05:53
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 22:05:53
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 01:04:29
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 01:04:29

US3732262

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:22:21

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:48
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:12
User entered '30 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 22:05:53
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 01:04:29

US3732262

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:22:21

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:48
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	23 Sep 2020 01:04:29

US3732262

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:22:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:48
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:58:12
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 22:05:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 22:05:53
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 22:05:53
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 01:04:29
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 01:04:29

US3732262

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:22:21

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:48
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 22:32:27
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Un-verified.	(b) (4) Lauren Arnett (b) (4)	18 Nov 2020 22:19:24
User entered '07 Oct 2020' reason for change: Data Entry Error	(b) (4) Lauren Arnett (b) (4)	18 Nov 2020 22:19:24
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:12
User entered '7 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 22:05:53
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 01:04:29

US3732262

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:22:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:55
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:15:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 23:54:25

US3732262

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:55
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:15:24
User entered '10 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 23:54:25

US3732262

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:55
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:15:24
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	22 Sep 2020 23:54:25

US3732262

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:22:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:55
User entered 'SICKD1'	System	22 Sep 2020 23:54:25

US3732262

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:47
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:15:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 01:05:27

US3732262

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:47
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:15:53
User entered '10 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 01:05:27

US3732262

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:47
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:15:53
User entered '12:15'	(b) (4), (b) (6)	23 Sep 2020 01:05:27

US3732262

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:47
User entered '10 Sep 2020 12:15'	System	23 Sep 2020 01:05:27

US3732262

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:47
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:15:53
User entered '161.6' cm	(b) (4), (b) (6)	23 Sep 2020 01:05:27
DataPoint set to visible.	System	22 Sep 2020 23:54:25

US3732262

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:47
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:15:53
User entered '81.0' kg	(b) (4), (b) (6)	23 Sep 2020 01:05:27
DataPoint set to visible.	System	22 Sep 2020 23:54:25

US3732262

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:47
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:15:53
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Sep 2020 01:05:33
User entered '100.0' F reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 01:05:33
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Sep 2020 01:05:27
User entered '100.0' (non-conformant).	(b) (4), (b) (6)	23 Sep 2020 01:05:27

US3732262

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:47
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:15:53
User entered 'Oral (Oral)'	(b) (4), (b) (6)	23 Sep 2020 01:05:27

US3732262

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:47
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:15:53
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 01:05:27

US3732262

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:47
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:15:53
User entered '73'	(b) (4), (b) (6)	23 Sep 2020 01:05:27

US3732262

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:47
User entered 'bpm'	System	23 Sep 2020 01:05:27

US3732262

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:47
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:15:53
User entered '16'	(b) (4), (b) (6)	23 Sep 2020 01:05:27

US3732262

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:47
User entered 'breaths/min'	System	23 Sep 2020 01:05:27

US3732262

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:47
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:15:53
User entered '143'	(b) (4), (b) (6)	23 Sep 2020 01:05:27

US3732262

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:47
User entered 'mmHg'	System	23 Sep 2020 01:05:27

US3732262

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:47
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:15:53
User entered '89'	(b) (4), (b) (6)	23 Sep 2020 01:05:27

US3732262

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:47
User entered 'mmHg'	System	23 Sep 2020 01:05:27

US3732262

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:47

US3732262

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:47

US3732262

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:22:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:37
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:16:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 01:05:45

US3732262

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:22:21

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:37
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:16:09
User entered '10 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 01:05:45

US3732262

Folder: Illness Visit Day 1 (1)

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

Generated On: 12 Aug 2021 13:22:21

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:30
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:16:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 01:05:54

US3732262

Folder: Illness Visit Day 1 (1)

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

Generated On: 12 Aug 2021 13:22:21

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:30
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:16:18
User entered '10 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 01:05:54

US3732262

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:22:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:20
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:17:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 16:51:45

US3732262

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:20
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:25:16
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 17:57:43
User entered '07 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 23:17:07
User entered '7 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 16:51:45

US3732262

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:20
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:17:07
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	08 Oct 2020 16:51:45

US3732262

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:22:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:20
User entered 'SICKD28'	System	08 Oct 2020 16:51:45

US3732262

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:17:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 22:01:42

US3732262

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:13
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 22:31:05
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Un-verified.	(b) (4) Lauren Arnett (b) (4)	18 Nov 2020 22:19:10
User entered '07 Oct 2020' reason for change: Data Entry Error	(b) (4) Lauren Arnett (b) (4)	18 Nov 2020 22:19:10
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 23:17:41
User entered '7 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 22:01:42

US3732262

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:17:41
User entered '14:05'	(b) (4), (b) (6)	13 Oct 2020 22:01:42

US3732262

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:13
User entered '07 Oct 2020 14:05'	System	18 Nov 2020 22:19:10
User entered '7 Oct 2020 14:05'	System	13 Oct 2020 22:01:42

US3732262

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:17:41
User entered '162.3' cm	(b) (4), (b) (6)	13 Oct 2020 22:01:42
DataPoint set to visible.	System	08 Oct 2020 16:51:45

US3732262

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:17:41
User entered '080.3' kg	(b) (4), (b) (6)	13 Oct 2020 22:01:42
DataPoint set to visible.	System	08 Oct 2020 16:51:45

US3732262

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 23:17:41
User entered '98.6' F	(b) (4), (b) (6)	13 Oct 2020 22:01:42

US3732262

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:17:41
User entered 'Oral (Oral)'	(b) (4), (b) (6)	13 Oct 2020 22:01:42

US3732262

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 23:17:41
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 22:01:42

US3732262

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:17:41
User entered '92'	(b) (4), (b) (6)	13 Oct 2020 22:01:42

US3732262

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:13
User entered 'bpm'	System	13 Oct 2020 22:01:42

US3732262

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:17:41
User entered '14'	(b) (4), (b) (6)	13 Oct 2020 22:01:42

US3732262

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:13
User entered 'breaths/min'	System	13 Oct 2020 22:01:42

US3732262

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:17:41
User entered '119'	(b) (4), (b) (6)	13 Oct 2020 22:01:42

US3732262

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:13
User entered 'mmHg'	System	13 Oct 2020 22:01:42

US3732262

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:17:41
User entered '70'	(b) (4), (b) (6)	13 Oct 2020 22:01:42

US3732262

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:13
User entered 'mmHg'	System	13 Oct 2020 22:01:42

US3732262

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:13

US3732262

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:13

US3732262

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:22:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:03
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:18:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 22:01:56

US3732262

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:22:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:03
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:18:07
User entered '7 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 22:01:56

US3732262

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 12 Aug 2021 13:22:21

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 23:18:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 22:02:12

US3732262

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 12 Aug 2021 13:22:21

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:56
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 22:31:51
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Un-verified.	(b) (4) Lauren Arnett (b) (4)	18 Nov 2020 22:19:16
User entered '07 Oct 2020' reason for change: Data Entry Error	(b) (4) Lauren Arnett (b) (4)	18 Nov 2020 22:19:16
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 23:18:18
User entered '7 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 22:02:12

US3732262

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

Form: Visit Date

Generated On: 12 Aug 2021 13:22:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:47:16
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
	(b) (4)	
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	23 Feb 2021 23:17:27
	(b) (4)	

US3732262

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

Form: Visit Date

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:47:16
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
User entered '23 Feb 2021'	Gordon Bovee (b) (4)	23 Feb 2021 23:17:27

US3732262

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

Form: Visit Date

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:47:16
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
	(b) (4)	
User entered 'Clinic (Clinic)'	Gordon Bovee (b) (4)	23 Feb 2021 23:17:27
	(b) (4)	

US3732262

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

Form: Visit Date

Generated On: 12 Aug 2021 13:22:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User entered 'UNBLND_DECIDE'	System	23 Feb 2021 23:17:27

US3732262

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

Form: Unblinding

Generated On: 12 Aug 2021 13:22:21

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:47:30
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
	(b) (4)	
User entered '23 Feb 2021'	Gordon Bovee (b) (4)	23 Feb 2021 23:19:53
	(b) (4)	

US3732262

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

Form: Unblinding

Generated On: 12 Aug 2021 13:22:21

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:06:31

US3732262

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

Form: Unblinding

Generated On: 12 Aug 2021 13:22:21

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:47:30
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	23 Feb 2021 23:19:53

US3732262

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

Form: Unblinding

Generated On: 12 Aug 2021 13:22:21

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:06:31

US3732262

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

Form: Unblinding

Generated On: 12 Aug 2021 13:22:21

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:47:30
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
	(b) (4)	
User entered '23 Feb 2021'	Gordon Bovee (b) (4)	23 Feb 2021 23:19:53
	(b) (4)	

US3732262

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

Form: Unblinding

Generated On: 12 Aug 2021 13:22:21

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:47:30
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
User entered 'mRNA-1273 (mRNA-1273)'	Gordon Bovee (b) (4)	23 Feb 2021 23:19:53

US3732262

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

Form: Unblinding

Generated On: 12 Aug 2021 13:22:21

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:47:30
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
User entered 'mRNA-1273 (mRNA-1273)'	Gordon Bovee (b) (4)	23 Feb 2021 23:19:53

US3732262

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

Form: Unblinding

Generated On: 12 Aug 2021 13:22:21

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:47:30
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
User entered 'Not Administered (NA)'	Gordon Bovee (b) (4)	23 Feb 2021 23:19:53

US3732262

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

Form: Unblinding

Generated On: 12 Aug 2021 13:22:21

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:47:30
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	23 Feb 2021 23:19:53

US3732262

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

Form: Unblinding

Generated On: 12 Aug 2021 13:22:21

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User entered empty.	System	23 Feb 2021 23:19:53

US3732262

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

Form: Unblinding

Generated On: 12 Aug 2021 13:22:21

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User entered 'I'	System	23 Feb 2021 23:19:53

US3732262

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:22:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:49:15
User entered empty.	Gordon Bovee (b) (4)	27 Feb 2021 01:08:17
	(b) (4)	

US3732262

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:22:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:49:15
User entered empty.	Gordon Bovee (b) (4)	27 Feb 2021 01:08:17
	(b) (4)	

US3732262

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:22:21

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User entered empty.	System	27 Feb 2021 01:08:17
DataPoint set to visible.	System	23 Feb 2021 23:19:53

US3732262

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:22:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:49:15
User entered empty.	Gordon Bovee (b) (4)	27 Feb 2021 01:08:17
	(b) (4)	

US3732262

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:22:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:49:15
User entered empty.	Gordon Bovee (b) (4)	27 Feb 2021 01:08:17
	(b) (4)	

US3732262

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:22:21

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User entered empty.	System	27 Feb 2021 01:08:17
DataPoint set to visible.	System	23 Feb 2021 23:19:53

US3732262

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User accepted default value 'Pre-Dose (PREDOSE)'	Gordon Bovee (b) (4)	27 Feb 2021 01:08:17
	(b) (4)	

US3732262

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:49:15
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	27 Feb 2021 01:08:17
	(b) (4)	

US3732262

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:49:15
User entered '26 Feb 2021'	Gordon Bovee (b) (4)	27 Feb 2021 01:08:17
	(b) (4)	

US3732262

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:49:15
User entered '14:41'	Gordon Bovee (b) (4)	27 Feb 2021 01:08:17
	(b) (4)	

US3732262

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User entered '26 Feb 2021 14:41'	System	27 Feb 2021 01:08:17

US3732262

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:49:15
User entered '98.2' F	Gordon Bovee (b) (4)	27 Feb 2021 01:08:17
	(b) (4)	

US3732262

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:49:15
User entered 'Oral (Oral)'	Gordon Bovee (b) (4)	27 Feb 2021 01:08:17
	(b) (4)	

US3732262

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:49:15
User entered empty.	Gordon Bovee (b) (4)	27 Feb 2021 01:08:17
	(b) (4)	

US3732262

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:49:15
User entered '75'	Gordon Bovee (b) (4)	27 Feb 2021 01:08:17
	(b) (4)	

US3732262

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User entered 'bpm'	System	27 Feb 2021 01:08:17

US3732262

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:49:15
User entered '16'	Gordon Bovee (b) (4)	27 Feb 2021 01:08:17
	(b) (4)	

US3732262

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User entered 'breaths/min'	System	27 Feb 2021 01:08:17

US3732262

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:49:15
User entered '143'	Gordon Bovee (b) (4)	27 Feb 2021 01:08:17
	(b) (4)	

US3732262

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User entered 'mmHg'	System	27 Feb 2021 01:08:17

US3732262

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:49:15
User entered '87'	Gordon Bovee (b) (4)	27 Feb 2021 01:08:17
	(b) (4)	

US3732262

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User entered 'mmHg'	System	27 Feb 2021 01:08:17

US3732262

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:22:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:49:15
User entered empty.	Gordon Bovee (b) (4)	27 Feb 2021 01:08:17
	(b) (4)	

US3732262

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:22:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:49:15
User entered empty.	Gordon Bovee (b) (4)	27 Feb 2021 01:08:17
	(b) (4)	

US3732262

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:22:21

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User entered empty.	System	27 Feb 2021 01:08:17
DataPoint set to visible.	System	23 Feb 2021 23:19:53

US3732262

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User accepted default value 'Post-Dose (POSTDOSE)'	Gordon Bovee (b) (4)	27 Feb 2021 01:08:17
	(b) (4)	

US3732262

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:49:15
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	27 Feb 2021 01:08:17
	(b) (4)	

US3732262

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:49:15
User entered '26 Feb 2021'	Gordon Bovee (b) (4)	27 Feb 2021 01:08:17
	(b) (4)	

US3732262

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:49:15
User entered '15:49'	Gordon Bovee (b) (4)	27 Feb 2021 01:08:17
	(b) (4)	

US3732262

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User entered '26 Feb 2021 15:49'	System	27 Feb 2021 01:08:17

US3732262

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:49:15
User entered '98' F	Gordon Bovee (b) (4)	27 Feb 2021 01:08:17
	(b) (4)	

US3732262

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:49:15
User entered 'Oral (Oral)'	Gordon Bovee (b) (4)	27 Feb 2021 01:08:17
	(b) (4)	

US3732262

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:49:15
User entered empty.	Gordon Bovee (b) (4)	27 Feb 2021 01:08:17
	(b) (4)	

US3732262

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:49:15
User entered '74'	Gordon Bovee (b) (4)	27 Feb 2021 01:08:17
	(b) (4)	

US3732262

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User entered 'bpm'	System	27 Feb 2021 01:08:17

US3732262

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:49:15
User entered '16'	Gordon Bovee (b) (4)	27 Feb 2021 01:08:17
	(b) (4)	

US3732262

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User entered 'breaths/min'	System	27 Feb 2021 01:08:17

US3732262

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:49:15
User entered '127'	Gordon Bovee (b) (4)	27 Feb 2021 01:08:17
	(b) (4)	

US3732262

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User entered 'mmHg'	System	27 Feb 2021 01:08:17

US3732262

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:49:15
User entered '88'	Gordon Bovee (b) (4)	27 Feb 2021 01:08:17
	(b) (4)	

US3732262

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User entered 'mmHg'	System	27 Feb 2021 01:08:17

US3732262

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

Form: Physical Examination

Generated On: 12 Aug 2021 13:22:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:50:03
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	27 Feb 2021 01:05:53
	(b) (4)	

US3732262

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

Form: Physical Examination

Generated On: 12 Aug 2021 13:22:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:50:03
User entered '26 Feb 2021'	Gordon Bovee (b) (4)	27 Feb 2021 01:05:53
	(b) (4)	

US3732262

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

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:21

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:50:16
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	27 Feb 2021 01:06:16
	(b) (4)	

US3732262

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

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:21

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:50:16
User entered '26 Feb 2021'	Gordon Bovee (b) (4)	27 Feb 2021 01:06:16
	(b) (4)	

US3732262

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

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:21

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:50:16
User entered 'Urine (URINE)'	Gordon Bovee (b) (4)	27 Feb 2021 01:06:16
	(b) (4)	

US3732262

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

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:21

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:50:16
User entered 'Negative (NEGATIVE)'	Gordon Bovee (b) (4)	27 Feb 2021 01:06:16
	(b) (4)	

US3732262

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

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:21

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:50:16
User entered 'No (N)'	Gordon Bovee (b) (4)	27 Feb 2021 01:06:16
	(b) (4)	

US3732262

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

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:21

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:50:16
User entered empty.	Gordon Bovee (b) (4)	27 Feb 2021 01:06:16
	(b) (4)	

US3732262

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

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:21

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:50:16
User entered empty.	Gordon Bovee (b) (4)	27 Feb 2021 01:06:16
	(b) (4)	

US3732262

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

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User entered empty.	System	27 Feb 2021 01:06:16

US3732262

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

Form: Exposure

Generated On: 12 Aug 2021 13:22:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:50:39
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	26 Feb 2021 23:41:06
	(b) (4)	

US3732262

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

Form: Exposure

Generated On: 12 Aug 2021 13:22:21

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:50:39
User entered empty.	Gordon Bovee (b) (4)	26 Feb 2021 23:41:06
	(b) (4)	

US3732262

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

Form: Exposure

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:50:39
User entered empty.	Gordon Bovee (b) (4)	26 Feb 2021 23:41:06
	(b) (4)	

US3732262

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

Form: Exposure

Generated On: 12 Aug 2021 13:22:21

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User entered 'mRNA-1273'	System	26 Feb 2021 23:41:06
DataPoint set to visible.	System	23 Feb 2021 23:19:53

US3732262

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

Form: Exposure

Generated On: 12 Aug 2021 13:22:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:50:39
User entered '26 Feb 2021'	Gordon Bovee (b) (4)	26 Feb 2021 23:41:06
	(b) (4)	

US3732262

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

Form: Exposure

Generated On: 12 Aug 2021 13:22:21

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:50:39
User entered '15:14'	Gordon Bovee (b) (4)	26 Feb 2021 23:41:06
	(b) (4)	

US3732262

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

Form: Exposure

Generated On: 12 Aug 2021 13:22:21

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User entered '26 Feb 2021 15:14'	System	26 Feb 2021 23:41:06

US3732262

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

Form: Exposure

Generated On: 12 Aug 2021 13:22:21

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:50:39
User entered 'Left Arm (LEFT ARM)'	Gordon Bovee (b) (4)	26 Feb 2021 23:41:06
	(b) (4)	

US3732262

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

Form: Exposure

Generated On: 12 Aug 2021 13:22:21

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:50:39
User entered 'ONCE'	System	26 Feb 2021 23:41:06

US3732262

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

Form: Exposure

Generated On: 12 Aug 2021 13:22:21

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User entered 'INTRAMUSCULAR'	System	26 Feb 2021 23:41:06

US3732262

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:22:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:51:17
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
	(b) (4)	
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	23 Feb 2021 23:33:02
	(b) (4)	

US3732262

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:22:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:51:17
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
	(b) (4)	
User entered '23 Feb 2021'	Gordon Bovee (b) (4)	23 Feb 2021 23:33:02
	(b) (4)	

US3732262

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:22:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:51:17
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
User entered '14:11'	Gordon Bovee (b) (4)	23 Feb 2021 23:33:02

US3732262

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:22:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User entered '23 Feb 2021 14:11'	System	23 Feb 2021 23:33:02

US3732262

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:22:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:51:27
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
	(b) (4)	
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	23 Feb 2021 23:33:14
	(b) (4)	

US3732262

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:22:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:51:27
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
	(b) (4)	
User entered '23 Feb 2021'	Gordon Bovee (b) (4)	23 Feb 2021 23:33:14
	(b) (4)	

US3732262

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:22:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:51:27
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
	(b) (4)	
User entered '14:14'	Gordon Bovee (b) (4)	23 Feb 2021 23:33:14
	(b) (4)	

US3732262

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:22:21

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User entered '23 Feb 2021 14:14'	System	23 Feb 2021 23:33:14

US3732262

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

Form: Continuing

Generated On: 12 Aug 2021 13:22:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:51:39
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	27 Feb 2021 01:09:56
	(b) (4)	

US3732262

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

Form: Continuing

Generated On: 12 Aug 2021 13:22:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:34
User entered '1'	System	27 Feb 2021 01:09:56

US3732262

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:12:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:56:07
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
User entered 'No (N)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	01 Apr 2021 21:44:29

US3732262

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:12:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:56:07
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
User entered empty.	(b) (4) Gordon Bovee (b) (4) (b) (4)	01 Apr 2021 21:44:29

US3732262

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:12:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:56:07
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
User entered empty.	(b) (4) Gordon Bovee (b) (4) (b) (4)	01 Apr 2021 21:44:29

US3732262

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:12:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:56:07
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
User entered empty.	(b) (4) Gordon Bovee (b) (4) (b) (4)	01 Apr 2021 21:44:29

US3732262

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:12:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:56:10
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
User entered 'Yes (Y)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	01 Apr 2021 21:44:35

US3732262

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:12:06
User entered 'I'	System	01 Apr 2021 21:44:35

US3732262

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:21

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:12:06
User entered '1'	System	01 Apr 2021 21:44:35
DataPoint set to visible.	System	01 Apr 2021 21:44:35

US3732262

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:22:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:53:17
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	01 Apr 2021 21:48:15

US3732262

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:53:17
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
User entered '30 Mar 2021'	Gordon Bovee (b) (4)	01 Apr 2021 21:48:15

US3732262

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:53:17
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
User entered 'Clinic (Clinic)'	Gordon Bovee (b) (4)	01 Apr 2021 21:48:15

US3732262

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:22:21

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD29'	System	01 Apr 2021 21:48:15

US3732262

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:53:45
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	01 Apr 2021 21:59:53

US3732262

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:53:45
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
User entered '30 Mar 2021'	Gordon Bovee (b) (4)	01 Apr 2021 21:59:53

US3732262

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:53:45
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
User entered '13:41'	Gordon Bovee (b) (4)	01 Apr 2021 21:59:53

US3732262

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Mar 2021 13:41'	System	01 Apr 2021 21:59:53

US3732262

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:53:45
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
User entered '98.2' F	Gordon Bovee (b) (4)	01 Apr 2021 21:59:53

US3732262

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:53:45
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
User entered 'Oral (Oral)'	Gordon Bovee (b) (4)	01 Apr 2021 21:59:53

US3732262

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:53:45
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
User entered empty.	Gordon Bovee (b) (4)	01 Apr 2021 21:59:53

US3732262

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:53:45
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
User entered '82'	Gordon Bovee (b) (4)	01 Apr 2021 21:59:53

US3732262

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Apr 2021 21:59:53

US3732262

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:53:45
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
User entered '19'	Gordon Bovee (b) (4)	01 Apr 2021 21:59:53

US3732262

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Apr 2021 21:59:53

US3732262

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:53:45
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
User entered '153'	Gordon Bovee (b) (4)	01 Apr 2021 21:59:53

US3732262

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Apr 2021 21:59:53

US3732262

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:53:45
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
User entered '97'	Gordon Bovee (b) (4)	01 Apr 2021 21:59:53

US3732262

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Apr 2021 21:59:53

US3732262

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:22:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:53:27
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	01 Apr 2021 21:52:23

US3732262

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:22:21

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:53:27
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
User entered '30 Mar 2021'	Gordon Bovee (b) (4)	01 Apr 2021 21:52:23

US3732262

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:22:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:53:52
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	01 Apr 2021 22:00:19

US3732262

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:22:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:53:52
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
User entered '30 Mar 2021'	Gordon Bovee (b) (4)	01 Apr 2021 22:00:19

US3732262

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:22:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:53:52
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
User entered '13:52'	Gordon Bovee (b) (4)	01 Apr 2021 22:00:19

US3732262

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:22:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Mar 2021 13:52'	System	01 Apr 2021 22:00:19

US3732262

Folder: Unscheduled 26 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 12 Aug 2021 13:22:21

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:43:52
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:53:41
User entered '26 Feb 2021'	Gordon Bovee (b) (4) (b) (4)	27 Feb 2021 01:08:50

US3732262

Folder: Unscheduled 26 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 12 Aug 2021 13:22:21

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:43:52
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:53:41
User entered '0'	Gordon Bovee (b) (4) (b) (4)	27 Feb 2021 01:08:50

US3732262

Folder: Unscheduled 26 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 12 Aug 2021 13:22:21

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:43:52
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:53:41
User entered 'I'	Gordon Bovee (b) (4) (b) (4)	27 Feb 2021 01:08:50

US3732262

Folder: Unscheduled 26 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 12 Aug 2021 13:22:21

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:43:52
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:53:41
User entered '0'	Gordon Bovee (b) (4) (b) (4)	27 Feb 2021 01:08:50

US3732262

Folder: Unscheduled 26 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 12 Aug 2021 13:22:21

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:43:52
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:53:41
User entered '0'	Gordon Bovee (b) (4) (b) (4)	27 Feb 2021 01:08:50

US3732262

Folder: Unscheduled 26 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:43:58
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:54:20
User entered 'Yes (Y)'	Gordon Bovee (b) (4) (b) (4)	27 Feb 2021 01:09:42

US3732262

Folder: Unscheduled 26 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:43:58
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:54:20
User entered '26 Feb 2021'	Gordon Bovee (b) (4) (b) (4)	27 Feb 2021 01:09:42

US3732262

Folder: Unscheduled 26 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:43:58
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:54:20
User entered '14:47'	Gordon Bovee (b) (4) (b) (4)	27 Feb 2021 01:09:42

US3732262

Folder: Unscheduled 26 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:43:58
User entered '26 Feb 2021 14:47'	System	27 Feb 2021 01:09:42

US3732262

Folder: Unscheduled 26 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:43:58
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:54:20
User entered '98.2' F	Gordon Bovee (b) (4) (b) (4)	27 Feb 2021 01:09:42

US3732262

Folder: Unscheduled 26 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:43:58
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:54:20
User entered 'Oral (Oral)'	Gordon Bovee (b) (4) (b) (4)	27 Feb 2021 01:09:42

US3732262

Folder: Unscheduled 26 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:43:58
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:54:20
User entered empty.	Gordon Bovee (b) (4) (b) (4)	27 Feb 2021 01:09:42

US3732262

Folder: Unscheduled 26 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:43:58
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:54:20
User entered '76'	Gordon Bovee (b) (4) (b) (4)	27 Feb 2021 01:09:42

US3732262

Folder: Unscheduled 26 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:43:58
User entered 'bpm'	System	27 Feb 2021 01:09:42

US3732262

Folder: Unscheduled 26 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:43:58
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:54:20
User entered '16'	Gordon Bovee (b) (4) (b) (4)	27 Feb 2021 01:09:42

US3732262

Folder: Unscheduled 26 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:43:58
User entered 'breaths/min'	System	27 Feb 2021 01:09:42

US3732262

Folder: Unscheduled 26 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:43:58
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:54:20
User entered '130'	Gordon Bovee (b) (4) (b) (4)	27 Feb 2021 01:09:42

US3732262

Folder: Unscheduled 26 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:43:58
User entered 'mmHg'	System	27 Feb 2021 01:09:42

US3732262

Folder: Unscheduled 26 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:43:58
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:54:20
User entered '85'	Gordon Bovee (b) (4) (b) (4)	27 Feb 2021 01:09:42

US3732262

Folder: Unscheduled 26 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:43:58
User entered 'mmHg'	System	27 Feb 2021 01:09:42

US3732262

Folder: Unscheduled 26 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:43:58

US3732262

Folder: Unscheduled 26 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:43:58

US3732262

Folder: Unscheduled 30 Mar 2021

Form: Unscheduled Visit Assessment

Generated On: 12 Aug 2021 13:22:21

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:44:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:46
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
User entered '30 Mar 2021'	(b) (4) Gordon Bovee (b) (4) (b) (4)	01 Apr 2021 21:55:39

US3732262

Folder: Unscheduled 30 Mar 2021

Form: Unscheduled Visit Assessment

Generated On: 12 Aug 2021 13:22:21

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:44:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:46
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
User entered '0'	(b) (4) Gordon Bovee (b) (4) (b) (4)	01 Apr 2021 21:55:39

US3732262

Folder: Unscheduled 30 Mar 2021

Form: Unscheduled Visit Assessment

Generated On: 12 Aug 2021 13:22:21

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:44:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:46
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
User entered 'l'	(b) (4) Gordon Bovee (b) (4) (b) (4)	01 Apr 2021 21:55:39

US3732262

Folder: Unscheduled 30 Mar 2021

Form: Unscheduled Visit Assessment

Generated On: 12 Aug 2021 13:22:21

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:44:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:46
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
User entered '0'	(b) (4) Gordon Bovee (b) (4) (b) (4)	01 Apr 2021 21:55:39

US3732262

Folder: Unscheduled 30 Mar 2021

Form: Unscheduled Visit Assessment

Generated On: 12 Aug 2021 13:22:21

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:44:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:46
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
User entered '0'	(b) (4) Gordon Bovee (b) (4) (b) (4)	01 Apr 2021 21:55:39

US3732262

Folder: Unscheduled 30 Mar 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:44:15
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:52:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
User entered 'Yes (Y)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	01 Apr 2021 21:56:32

US3732262

Folder: Unscheduled 30 Mar 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:44:15
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:52:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
User entered '30 Mar 2021'	(b) (4) Gordon Bovee (b) (4) (b) (4)	01 Apr 2021 21:56:32

US3732262

Folder: Unscheduled 30 Mar 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:44:15
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:52:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
User entered '13:49'	(b) (4) Gordon Bovee (b) (4) (b) (4)	01 Apr 2021 21:56:32

US3732262

Folder: Unscheduled 30 Mar 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:44:15
User entered '30 Mar 2021 13:49'	System	01 Apr 2021 21:56:32

US3732262

Folder: Unscheduled 30 Mar 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:44:15
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:52:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
User entered '98.2' F	(b) (4) Gordon Bovee (b) (4) (b) (4)	01 Apr 2021 21:56:32

US3732262

Folder: Unscheduled 30 Mar 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:44:15
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:52:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
User entered 'Oral (Oral)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	01 Apr 2021 21:56:32

US3732262

Folder: Unscheduled 30 Mar 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:44:15
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:52:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
User entered empty.	(b) (4) Gordon Bovee (b) (4) (b) (4)	01 Apr 2021 21:56:32

US3732262

Folder: Unscheduled 30 Mar 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:44:15
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:52:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
User entered '85'	(b) (4) Gordon Bovee (b) (4) (b) (4)	01 Apr 2021 21:56:32

US3732262

Folder: Unscheduled 30 Mar 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:44:15
User entered 'bpm'	System	01 Apr 2021 21:56:32

US3732262

Folder: Unscheduled 30 Mar 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:44:15
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:52:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
User entered '19'	(b) (4) Gordon Bovee (b) (4) (b) (4)	01 Apr 2021 21:56:32

US3732262

Folder: Unscheduled 30 Mar 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:44:15
User entered 'breaths/min'	System	01 Apr 2021 21:56:32

US3732262

Folder: Unscheduled 30 Mar 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:44:15
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:52:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
User entered '144'	(b) (4) Gordon Bovee (b) (4) (b) (4)	01 Apr 2021 21:56:32

US3732262

Folder: Unscheduled 30 Mar 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:44:15
User entered 'mmHg'	System	01 Apr 2021 21:56:32

US3732262

Folder: Unscheduled 30 Mar 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:44:15
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:52:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:26:17
User entered '93'	(b) (4) Gordon Bovee (b) (4) (b) (4)	01 Apr 2021 21:56:32

US3732262

Folder: Unscheduled 30 Mar 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:44:15
User entered 'mmHg'	System	01 Apr 2021 21:56:32

US3732262

Folder: Unscheduled 30 Mar 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:44:15

US3732262

Folder: Unscheduled 30 Mar 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:44:15

US3732262

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 13:22:21

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:56:21
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:59:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Sep 2020 21:23:28

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:21

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:00:51
User closed query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment.' (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 17:53:54
Query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment.' answered with 'updating' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 23:26:29
User opened query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment.' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 18:43:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:26:28
User entered 'USA-US102-2020-mRNA-1273-P301000001'	System	10 Sep 2020 16:25:56
User entered 'New'	(b) (4), (b) (6)	10 Sep 2020 16:25:56

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:21

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 21:38:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 21:38:17
Data point term sent to Coder	System	23 Nov 2020 20:59:21
Query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding.	Coder Import (b) (4)	23 Nov 2020 20:59:04
' canceled (Site from System).		
User opened query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding.	Coder Import (b) (4)	23 Nov 2020 12:23:56
' (Site from System).		
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:00:51
User closed query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 13:57:16
Query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 20:18:06
User opened query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 15:51:01
User closed query 'PV Query: Please provide results of the baseline SARS-CoV-2 RT-PCR, and date results were received.' (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 17:54:17
User closed query 'PV query: Please clarify if subject was symptomatic prior receiving the first dose of study medication.' (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 17:54:11

PRODUCTION RELEASE (v12.003
EAB) (1725)

2283 of 2563

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:21

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 17:54:04
Query 'PV Query: Please provide results of the baseline SARS-CoV-2 RT-PCR, and date results were received.' answered with 'Baseline PCR was collected on 02SEP2020. Resulted as Positive on 08SEP2020' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 23:24:03
Query 'PV query: Please clarify if subject was symptomatic prior receiving the first dose of study medication.' answered with 'Confirming subject was not symptomatic prior to receiving their first dose of IP ' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 23:21:20
Query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' answered with 'confirming subject did not have any known exposure COVID-19 or risk factors at the time of screening/baseline' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 23:18:46
User opened query 'PV Query: Please provide results of the baseline SARS-CoV-2 RT-PCR, and date results were received.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 15:29:43
User opened query 'PV query: Please clarify if subject was symptomatic prior receiving the first dose of study medication.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 15:28:56
Query 'Safety Medical Query: Please provide results of the baseline SARS-CoV-2 RT-PCR, and date results were received.' canceled (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 15:28:08
Query 'Safety Medical Query: Please clarify if subject was symptomatic prior receiving the first dose of study medication.' canceled (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 15:27:56
User opened query 'Safety Medical Query: Please provide results of the baseline SARS-CoV-2 RT-PCR, and date results were received.' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 18:46:44
User opened query 'Safety Medical Query: Please clarify if subject was symptomatic prior receiving the first dose of study medication.' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 18:46:36
User opened query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 18:44:51

PRODUCTION RELEASE (v12.003
EAB) (1725)

2284 of 2563

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:21

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 06:17:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 06:17:34
Data point term sent to Coder	System	09 Sep 2020 22:21:54
User entered 'Symptomatic COVID-19'	(b) (4), (b) (6)	09 Sep 2020 22:20:54

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:00:51
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 20:11:11
User entered 'No (N)'	(b) (4), (b) (6)	09 Sep 2020 22:20:54

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:00:51
User entered 'No (N)'	(b) (4), (b) (6)	09 Sep 2020 22:20:54

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:00:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Sep 2020 22:20:54

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
User closed query 'PV Query: Please confirm the start date of the SAE. The start date of the SAE should be when symptoms first are present.' (Site from Safety).	(b) (4), (b) (6)	07 Nov 2020 00:13:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:00:51
Query 'PV Query: Please confirm the start date of the SAE. The start date of the SAE should be when symptoms first are present.' answered with 'correct as is. Site was unaware when the symptoms first started, until positive baseline results were received and site called subject to notify of results.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 18:19:34
User opened query 'PV Query: Please confirm the start date of the SAE. The start date of the SAE should be when symptoms first are present.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 13:25:19
Query 'PV Query: Please confirm the start date of the SAE. The start date of the SAE should be when symptoms first are present.' canceled (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 13:25:02
User opened query 'PV Query: Please confirm the start date of the SAE. The start date of the SAE should be when symptoms first are present.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 15:52:48
User entered '06 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 23:13:42
User entered '02 Sep 2020'	(b) (4), (b) (6)	09 Sep 2020 22:20:54

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:00:51
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 23:13:42
User entered '15:38'	(b) (4), (b) (6)	09 Sep 2020 22:20:54

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 23:13:42
User entered '02 Sep 2020 15:38'	System	09 Sep 2020 22:20:54

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:00:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 20:11:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Sep 2020 22:20:54

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:00:51
User entered '19 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 20:11:11
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 22:20:54

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:21

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:00:51
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 22:20:54

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (when symptoms have resolved).' canceled (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 13:25:09
User opened query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 18:43:43
User entered empty.	System	09 Sep 2020 22:20:54

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:21

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:00:51
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	09 Sep 2020 22:20:54

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:00:51
User entered 'No (N)'	(b) (4), (b) (6)	09 Sep 2020 22:20:54

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:00:51
User entered '0'	(b) (4), (b) (6)	09 Sep 2020 22:20:54

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:00:51
User entered '0'	(b) (4), (b) (6)	09 Sep 2020 22:20:54

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:00:51
User entered '0'	(b) (4), (b) (6)	09 Sep 2020 22:20:54

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:00:51
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 22:20:54

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:21

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:00:51
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 22:20:54

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:00:51
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 22:20:54

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:00:51
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 22:20:54

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:00:51
User entered '0'	(b) (4), (b) (6)	09 Sep 2020 22:20:54

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:00:51
User entered '0'	(b) (4), (b) (6)	09 Sep 2020 22:20:54

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:00:51
User entered '0'	(b) (4), (b) (6)	09 Sep 2020 22:20:54

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
User closed query 'PV Query: Not applicable is not appropriate causality assessment. Per protocol, answer should be either a yes or no. Please provide the investigator's causality assessment between the event and the study drug' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:13:46
	(b) (4), (b) (6)	06 Nov 2020 23:00:51
User closed query 'Per MM, please confirm the relationship and action taken with investigational product, as the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 04:07:07
Query 'Per MM, please confirm the relationship and action taken with investigational product, as the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 19:03:33
Query 'PV Query: Not applicable is not appropriate causality assessment. Per protocol, answer should be either a yes or no. Please provide the investigator's causality assessment between the event and the study drug' answered with 'Updated' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 19:03:27
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 19:03:08
User opened query 'Per MM, please confirm the relationship and action taken with investigational product, as the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses' (Site from DM).	(b) (4), (b) (6)	17 Oct 2020 13:22:38
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 15:52:18
User opened query 'PV Query: Not applicable is not appropriate causality assessment. Per protocol, answer should be either a yes or no. Please provide the investigator's causality assessment between the event and the study drug' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 18:46:05

PRODUCTION RELEASE (v12.003
EAB) (1725)

2308 of 2563

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 18:45:31
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	09 Sep 2020 22:57:16
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 22:57:16
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	09 Sep 2020 22:20:54
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Sep 2020 22:20:54

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:00:51
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Sep 2020 22:20:54

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:21

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
User closed query 'Per CDM: Dose discontinuation form has not been completed. Please reconcile. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 15:08:16
User closed query 'Per MM, please confirm the relationship and action taken with investigational product, as the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 15:08:14
User closed query 'PV Query: Please confirm if the subject is scheduled to receive further IP doses? If no, please appropriately update Action Taken from None to Withdrawn per protocol.' (Site from Safety).	(b) (4), (b) (6)	07 Nov 2020 00:13:37
Query 'Per MM, please confirm the relationship and action taken with investigational product, as the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses ' answered with 'Correct as is. AE is not related to IP and IP for 2nd dose was withdrawn' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 23:54:19
Query 'Per CDM: Dose discontinuation form has not been completed. Please reconcile. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 23:53:22
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:00:51
User opened query 'Per MM, please confirm the relationship and action taken with investigational product, as the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 19:04:47
User opened query 'Per CDM: Dose discontinuation form has not been completed. Please reconcile. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:30:26
Query 'PV Query: Please confirm if the subject is scheduled to receive further IP doses? If no, please appropriately update Action Taken from None to Withdrawn per protocol.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 19:03:38

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:21

Action taken with investigational product

Audit	User	Time (GMT)
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 19:03:16
User closed query 'Per MM, please confirm if action taken with IP is correct, per protocol sec 7.2, if the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses of vaccine but will be encouraged to continue study participation for safety through 24 months following last dose.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 10:09:39
User opened query 'PV Query: Please confirm if the subject is scheduled to receive further IP doses? If no, please appropriately update Action Taken from None to Withdrawn per protocol.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 16:52:06
User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 14:14:40
Query 'Per MM, please confirm if action taken with IP is correct, per protocol sec 7.2, if the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses of vaccine but will be encouraged to continue study participation for safety through 24 months following last dose.' answered with 'Per CRA, correct as is.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 17:24:27
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' answered with 'Per CRA, correct a is.' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 17:24:08
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 17:23:43
User opened query 'Per MM, please confirm if action taken with IP is correct, per protocol sec 7.2, if the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses of vaccine but will be encouraged to continue study participation for safety through 24 months following last dose.' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 18:33:36

PRODUCTION RELEASE (v12.003
EAB) (1725)

2312 of 2563

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 15:52:24
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 22:57:16
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4), (b) (6)	09 Sep 2020 22:20:54

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:21

None

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:00:51
User closed query 'Per DM CLR: Other Action Taken = NONE. However, there is a Con Med recorded that has this AE as its indication. Please review and update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 10:10:05
Query 'Per DM CLR: Other Action Taken = NONE. However, there is a Con Med recorded that has this AE as its indication. Please review and update eCRF as appropriate.' answered with 'Updated.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 17:20:33
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 17:20:10
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 17:54:29
User opened query 'Per DM CLR: Other Action Taken = NONE. However, there is a Con Med recorded that has this AE as its indication. Please review and update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 14:06:32
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'please refer to medication list' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 23:27:06

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:21

None

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 18:44:30
User entered 'I'	(b) (4), (b) (6)	09 Sep 2020 22:20:54

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:00:51
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 17:20:10
User entered '0'	(b) (4), (b) (6)	09 Sep 2020 22:20:54

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:00:51
User entered '0'	(b) (4), (b) (6)	09 Sep 2020 22:20:54

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:21

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:00:51
User closed query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 14:14:51
Query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' answered with 'Updated.' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 17:20:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 17:20:10
User opened query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 18:44:09
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 14:47:02
Query 'Data is required. Please complete.' answered with 'will be updated upon resolution' (Site from System).	(b) (4), (b) (6)	09 Sep 2020 22:59:53
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 22:20:54
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 22:20:54

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:00:51
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 22:20:54

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:21

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:00:51
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 22:20:54

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:21

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Sep 2020 22:20:54

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 20:11:11
User entered '0'	System	09 Sep 2020 22:20:54

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:56:21
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
User closed query 'Per DM CLR: Per Diary Dose 1 Day 1, Pain at Injection Site and Underarm Gland Swelling or Tenderness Day 2, Pain at Injection Site and Underarm Gland Swelling or Tenderness Day 3, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM). Query 'Per DM CLR: Per Diary Dose 1 Day 1, Pain at Injection Site and Underarm Gland Swelling or Tenderness Day 2, Pain at Injection Site and Underarm Gland Swelling or Tenderness Day 3, Pain at Injection Site = 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 'Per verbal report with subject at Day 8 Safety Call, medication only taken on day 3 (already recorded in Con Meds).' (Site from DM). User opened query 'Per DM CLR: Per Diary Dose 1 Day 1, Pain at Injection Site and Underarm Gland Swelling or Tenderness Day 2, Pain at Injection Site and Underarm Gland Swelling or Tenderness Day 3, Pain at Injection Site = 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)	10 Feb 2021 03:58:54
	(b) (4), (b) (6)	09 Feb 2021 20:21:49
	(b) (4), (b) (6)	27 Jan 2021 11:17:56

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Per Diary Dose 1 Day 1-3 Pain at Injection Site; Day 1-2 Underarm Gland Swelling or Tenderness; and Day 4, 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)	09 Nov 2020 15:08:44
Query 'Per DM CLR: Per Diary Dose 1 Day 1-3 Pain at Injection Site; Day 1-2 Underarm Gland Swelling or Tenderness; and Day 4, 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 'Please refer to log line # 3- Tylenol previously recorded for headache ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 23:59:15
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:01:17
User opened query 'Per DM CLR: Per Diary Dose 1 Day 1-3 Pain at Injection Site; Day 1-2 Underarm Gland Swelling or Tenderness; and Day 4, 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)	06 Nov 2020 16:11:55
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:38:16

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:22:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:41:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:41:38
Data point term sent to Coder	System	04 Sep 2020 18:40:32
User entered 'losartan'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:39:32

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:22:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:39:32

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:22:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 19:22:10
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'Reviewed and updated, per source.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 22:12:53
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 11:01:17
User entered 'hypertension'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:39:32

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:22:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered '50'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:39:32

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:22:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'mg (mg)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:39:32

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:22:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered empty.	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:39:32

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:22:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'once daily (QD)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:39:32

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:22:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered empty.	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:39:32

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:22:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:39:32

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:22:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered empty.	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:39:32

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:22:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'un Jun 2020'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:39:32

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:22:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered '0'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:39:32

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:22:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:39:32

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:22:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered empty.	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:39:32

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:22:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:39:32

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:22:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 18:39:32

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:22:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 18:39:32

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:22:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 18:39:32

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:22:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:41:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:41:38
Data point term sent to Coder	System	04 Sep 2020 18:40:37
User entered 'ibuprofen'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:40:03

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:22:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:40:03

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:22:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'migraine headaches'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:40:03

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:22:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered '800'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:40:03

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:22:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'mg (mg)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:40:03

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:22:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered empty.	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:40:03

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:22:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'as needed (PRN)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:40:03

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:22:21

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered empty.	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:40:03

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:22:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:40:03

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:22:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered empty.	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:40:03

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:22:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'un UNK 2017'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:40:03

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:22:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered '0'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:40:03

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:22:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:40:03

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered empty.	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:40:03

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:22:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	04 Sep 2020 18:40:03

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:22:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 18:40:03

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:22:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 18:40:03

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:22:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 18:40:03

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:22:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:15:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:15:43
Data point term sent to Coder	System	11 Sep 2020 17:15:21
User entered 'tylenol'	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 17:15:12

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:22:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 17:15:12

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:22:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the Headache is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of Headache did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 19:22:33
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the Headache is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of Headache did not meet the AE reporting criteria.' answered with 'correct as is, no AE to be opened as AR did not meet reporting criteria however subject did take medication for AR' (Site from DM).	Lauren Arnett (b) (4) (b) (4)	20 Oct 2020 15:46:18

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:22:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered '500'	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 17:15:12

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:22:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'mg (mg)'	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 17:15:12

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:22:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered empty.	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 17:15:12

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:22:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'as needed (PRN)'	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 17:15:12

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:22:21

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered empty.	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 17:15:12

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:22:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 17:15:12

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:22:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered empty.	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 17:15:12

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:22:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered '04 Sep 2020'	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 17:15:12

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:22:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered '0'	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 17:15:12

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:22:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 17:15:12

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered '04 Sep 2020'	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 17:15:12

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:22:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 17:15:12

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:22:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 17:15:12

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:22:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 17:15:12

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:22:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 17:15:12

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:22:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 19:05:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 19:05:49
Data point term sent to Coder	System	15 Sep 2020 19:05:00
User entered 'tylenol'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 19:04:45

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:22:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 19:04:45

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:22:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User closed query 'Per DM CLR: Please update Indication to specify the sign/symptom experienced by the patient. Please update all applicable details as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 19:22:43
Query 'Per DM CLR: Please update Indication to specify the sign/symptom experienced by the patient. Please update all applicable details as appropriate. ' answered with 'correct as is, per clarification AE of confirmed COVID is to be opened as "symptomatic covid-19" ' (Site from DM).	Lauren Arnett (b) (4) (b) (4)	20 Oct 2020 15:47:15
User opened query 'Per DM CLR: Please update Indication to specify the sign/symptom experienced by the patient. Please update all applicable details as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 11:02:49
User entered 'symptomatic covid-19'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 19:04:45

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:22:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered '500'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 19:04:45

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:22:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'mg (mg)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 19:04:45

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:22:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered empty.	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 19:04:45

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:22:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'as needed (PRN)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 19:04:45

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:22:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered empty.	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 19:04:45

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:22:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 19:04:45

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:22:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered empty.	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 19:04:45

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered '12 Sep 2020'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 19:04:45

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:22:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered '0'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 19:04:45

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:22:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'No (N)' reason for change: New Information	Lauren Arnett (b) (4) (b) (4)	20 Oct 2020 15:48:23
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 19:04:45

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered '19 Sep 2020' reason for change: New Information	Lauren Arnett (b) (4) (b) (4)	20 Oct 2020 15:48:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 19:04:45

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:22:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:02:53
User closed query '	(b) (4), (b) (6)	06 Nov 2020 04:07:37
Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate.' (Site from DM).		
Query '	(b) (4), (b) (6)	05 Nov 2020 19:13:10
Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate.' answered with 'updated ' (Site from DM).		
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 19:13:05
User opened query '	(b) (4), (b) (6)	30 Oct 2020 10:11:36
Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate.' (Site from DM).		
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	15 Sep 2020 19:04:45
	(b) (4)	

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:22:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 19:04:45

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:22:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 19:04:45

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:22:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 19:04:45

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:22:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 20:16:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 20:16:41
Data point term sent to Coder	System	30 Sep 2020 20:15:40
User entered 'TYLENOL'	(b) (4), (b) (6)	30 Sep 2020 20:14:49

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:22:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 20:14:49

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:22:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User closed query 'Per DM CLR: Please review Indication and please note, there is no corresponding AE record that match this condition. Please update to record the corresponding AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 04:08:02
Query 'Per DM CLR: Please review Indication and please note, there is no corresponding AE record that match this condition. Please update to record the corresponding AE as appropriate. Otherwise, clarify.' answered with 'indication is medical history' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 19:14:59
User opened query 'Per DM CLR: Please review Indication and please note, there is no corresponding AE record that match this condition. Please update to record the corresponding AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 19:29:06
User entered 'MENSTRUAL CRAMPS'	(b) (4), (b) (6)	30 Sep 2020 20:14:49

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:22:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered '500'	(b) (4), (b) (6)	30 Sep 2020 20:14:49

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:22:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'mg (mg)'	(b) (4), (b) (6)	30 Sep 2020 20:14:49

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:22:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 20:14:49

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:22:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'as needed (PRN)'	(b) (4), (b) (6)	30 Sep 2020 20:14:49

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:22:21

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 20:14:49

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:22:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 20:15:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 20:15:02
User entered 'Oral (ORAL)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 20:15:02
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 20:14:49
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 20:14:49

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:22:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 20:14:49

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:22:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'UN UNK 2014'	(b) (4), (b) (6)	30 Sep 2020 20:14:49

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:22:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 20:14:49

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:22:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 20:14:49

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 20:14:49

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:22:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 20:14:49

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:22:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 20:14:49

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:22:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 20:14:49

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:22:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 20:14:49

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:22:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 07:21:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 07:21:22
Data point term sent to Coder	System	13 Oct 2020 22:09:31
User entered 'IBUPROFEN'	(b) (4), (b) (6)	13 Oct 2020 22:09:17

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:22:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 22:09:17

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:22:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:02:53
User closed query 'Per DM CLR: Please review Indication and please note, there is no corresponding MH or AE record that match this condition. Please update to record the corresponding MH or AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 04:08:45
Query 'Per DM CLR: Please review Indication and please note, there is no corresponding MH or AE record that match this condition. Please update to record the corresponding MH or AE as appropriate. Otherwise, clarify.' answered with 'indication is medical history' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 19:15:38
User opened query 'Per DM CLR: Please review Indication and please note, there is no corresponding MH or AE record that match this condition. Please update to record the corresponding MH or AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 19:29:50
User entered 'LEFT SPRAINED ANKLE'	(b) (4), (b) (6)	13 Oct 2020 22:09:17

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:22:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered '800'	(b) (4), (b) (6)	13 Oct 2020 22:09:17

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:22:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Oct 2020 22:09:17

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:22:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 22:09:17

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:22:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'as needed (PRN)'	(b) (4), (b) (6)	13 Oct 2020 22:09:17

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:22:21

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 22:09:17

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:22:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 22:09:17

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:22:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 22:09:17

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:22:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'UN Mar 2020' reason for change: Data Entry Error	Lauren Arnett (b) (4)	20 Oct 2020 15:49:00
User entered 'UN UNK 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 22:09:17

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:22:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 22:09:17

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:22:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 22:09:17

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 22:09:17

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:22:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 22:09:17

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:22:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 22:09:17

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:22:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 22:09:17

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:22:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 22:09:17

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:22:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 20:28:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 19:30:22
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 Nov 2020 19:30:22
Data point term sent to Coder	System	05 Nov 2020 19:29:48
User entered 'flu vaccine'	Lauren Arnett (b) (4) (b) (4)	05 Nov 2020 19:29:06

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:22:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 20:28:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	05 Nov 2020 19:29:06
	(b) (4)	

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:22:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 20:28:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'influenza'	Lauren Arnett (b) (4)	05 Nov 2020 19:29:06
	(b) (4)	

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:22:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 20:28:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered '0.5'	Lauren Arnett (b) (4) (b) (4)	05 Nov 2020 19:29:06

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:22:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 20:28:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'mL (mL)'	Lauren Arnett (b) (4)	05 Nov 2020 19:29:06
	(b) (4)	

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:22:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 20:28:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered empty.	Lauren Arnett (b) (4)	05 Nov 2020 19:29:06
	(b) (4)	

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:22:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 20:28:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'once (ONCE)'	Lauren Arnett (b) (4)	05 Nov 2020 19:29:06
	(b) (4)	

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:22:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 20:28:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered empty.	Lauren Arnett (b) (4)	05 Nov 2020 19:29:06
	(b) (4)	

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:22:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 20:28:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'Intramuscular (INTRAMUSCULAR)'	Lauren Arnett (b) (4)	05 Nov 2020 19:29:06
	(b) (4)	

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:22:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 20:28:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered empty.	Lauren Arnett (b) (4)	05 Nov 2020 19:29:06
	(b) (4)	

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:22:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 20:28:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered '16 Oct 2020'	Lauren Arnett (b) (4)	05 Nov 2020 19:29:06
	(b) (4)	

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:22:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 20:28:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered '0'	Lauren Arnett (b) (4)	05 Nov 2020 19:29:06
	(b) (4)	

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:22:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 20:28:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'No (N)'	Lauren Arnett (b) (4)	05 Nov 2020 19:29:06
	(b) (4)	

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:22:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 20:28:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered '16 Oct 2020'	Lauren Arnett (b) (4)	05 Nov 2020 19:29:06
	(b) (4)	

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:22:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 20:28:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:02:53
User entered 'No (N)'	Lauren Arnett (b) (4)	05 Nov 2020 19:29:06
	(b) (4)	

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:22:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 20:28:56
User entered empty.	System	05 Nov 2020 19:29:06

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:22:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 20:28:56
User entered empty.	System	05 Nov 2020 19:29:06

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:22:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 20:28:56
User entered empty.	System	05 Nov 2020 19:29:06

US3732262

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 12 Aug 2021 13:22:21

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:04:18
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:44:55

US3732262

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:22:21

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:28:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:04:08
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
User closed query 'Per CDM: Data is missing from End of Study/Study Discontinuation. Please complete.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 03:22:26
Query 'Per CDM: Data is missing from End of Study/Study Discontinuation. Please complete.' answered with 'Dose discontinued but subject is still enrolled in study.' (Site from DM).		09 Feb 2021 20:15:16
User opened query 'Per CDM: Data is missing from End of Study/Study Discontinuation. Please complete.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 13:28:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	12 Jan 2021 18:38:30
User entered '06 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Jan 2021 16:32:26
Query 'Data is required. Please complete.' answered with 'data entered in error ' (Site from System).	Amara Yilmaz (b) (4)	11 Jan 2021 21:16:43
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	11 Jan 2021 21:16:14
User entered '06 Sep 2020'	Amara Yilmaz (b) (4)	11 Jan 2021 21:16:14
	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:52:10

US3732262

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:22:21

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:28:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:04:08
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	(b) (4), (b) (6)
User closed query 'Per CDM Re-query: As per client, If Dosing Discontinuation is due to COVID-19 then, Primary reason for dosing discontinuation should be selected as "Due to SARS COV-2". Kindly update as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 18:38:29
		12 Jan 2021 18:38:27
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Jan 2021 16:32:26
Query 'Data is required. Please complete.' answered with 'data entered in error' (Site from System).	Amara Yilmaz (b) (4)	11 Jan 2021 21:17:02
	(b) (4)	
Query 'Per CDM Re-query: As per client, If Dosing Discontinuation is due to COVID-19 then, Primary reason for dosing discontinuation should be selected as "Due to SARS COV-2". Kindly update as appropriate.' answered with 'data entered in error' (Site from DM).	Amara Yilmaz (b) (4)	11 Jan 2021 21:16:47
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Jan 2021 21:16:14
User entered empty; reason for change Data Entry Error	Amara Yilmaz (b) (4)	11 Jan 2021 21:16:14
	(b) (4)	
User opened query 'Per CDM Re-query: As per client, If Dosing Discontinuation is due to COVID-19 then, Primary reason for dosing discontinuation should be selected as "Due to SARS COV-2". Kindly update as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:21:34
Query 'Per CDM Re-query: As per client, Id Dosing Discontinuation is due to COVID-19 then, Primary reason for dosing discontinuation should be selected as "Due to SARS COV-2". Kindly update as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:21:23

US3732262

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:22:21

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User opened query 'Per CDM Re-query: As per client, Id Dosing Discontinuation is due to COVID-19 then, Primary reason for dosing discontinuation should be selected as "Due to SARS COV-2". Kindly update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:21:16
User closed query 'Per CDM; Please consider selecting 'Due to SARS-CoV-2' and make all appropriate updates' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:20:01
Query 'Per CDM; Please consider selecting 'Due to SARS-CoV-2' and make all appropriate updates' answered with 'correct as is. per previous directive of name of term for AE' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 22:53:14
User opened query 'Per CDM; Please consider selecting 'Due to SARS-CoV-2' and make all appropriate updates' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:46:24
User entered 'AE (specify) (ADVERSE EVENT)'	(b) (4), (b) (6)	06 Nov 2020 23:52:10

US3732262

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:22:21

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:28:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:04:08
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:25:46
User closed query 'Per CDM: Per sponsor review, if reason for dosing discontinuation is AE/SAE, then AE specify field must include '#' symbol and 'AE logline number'. Please consider updating AE specify field to include only the '#' symbol and 'AE logline number' (i.e. #1 for row 1).' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 06:19:24
Query 'Per CDM: Per sponsor review, if reason for dosing discontinuation is AE/SAE, then AE specify field must include '#' symbol and 'AE logline number'. Please consider updating AE specify field to include only the '#' symbol and 'AE logline number' (i.e. #1 for row 1).' answered with 'updated' (Site from DM).	Gordon Bovee (b) (4)	22 Mar 2021 23:29:01
Signature has been broken.	Gordon Bovee (b) (4)	22 Mar 2021 23:28:53
User entered 'SYMPTOMATIC COVID-19 AE #1' reason for change: Per Query Resolution	Gordon Bovee (b) (4)	22 Mar 2021 23:28:53
User opened query 'Per CDM: Per sponsor review, if reason for dosing discontinuation is AE/SAE, then AE specify field must include '#' symbol and 'AE logline number'. Please consider updating AE specify field to include only the '#' symbol and 'AE logline number' (i.e. #1 for row 1).' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 15:27:44
Query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 15:27:23
User opened query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:17:12
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
User entered 'symptomatic covid-19' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Jan 2021 16:32:26

US3732262

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:22:21

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amara Yilmaz (b) (4)	11 Jan 2021 21:16:14
User entered 'Symptomatic COVID-19'	(b) (4), (b) (6)	06 Nov 2020 23:52:10

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'USA-US102-2020-MRNA-1273-P301000001'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
Amendment Manager: User entered 'Scott'	System	14 Sep 2020 21:58:34
User entered 'Jeffrey'	Lauren Arnett (b) (4)	10 Sep 2020 19:13:45
	(b) (4)	

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
User entered 'Overcash'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 19:13:45

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
Amendment Manager: User entered '5565 Grossmont Center Dr'	System	14 Sep 2020 21:58:34
User entered '5565 Grossmont Center Dr. BLD 2 Suite 1'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 19:13:45

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
User entered 'La Mesa'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 19:13:45

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
User entered 'CA'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 19:13:45

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
User entered '91942'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 19:13:45

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:57:47
Un-reviewed for Safety.	System	23 Sep 2020 17:55:57
User entered 'US'	System	23 Sep 2020 17:55:57
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
User entered empty; reason for change Data Entry Error	Lauren Arnett (b) (4)	10 Sep 2020 19:17:53
User entered 'US' (non-conformant).	System	10 Sep 2020 16:43:31

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
	(b) (4)	
User entered '5'	System	07 Nov 2020 00:14:22
User entered '4'	System	15 Oct 2020 14:15:10
User entered '3'	System	08 Oct 2020 13:57:59
User entered '2'	System	23 Sep 2020 17:55:57
User entered '1'	System	10 Sep 2020 16:43:31

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'USA-US102-2020-MRNA-1273-P301000001'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
Amendment Manager: User entered 'Scott'	System	14 Sep 2020 21:58:34
User entered 'Jeffrey'	Lauren Arnett (b) (4)	10 Sep 2020 19:13:45
	(b) (4)	

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
User entered 'Overcash'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 19:13:45

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
Amendment Manager: User entered '5565 Grossmont Center Dr'	System	14 Sep 2020 21:58:34
User entered '5565 Grossmont Center Dr. BLD 2 Suite 1'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 19:13:45

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
User entered 'La Mesa'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 19:13:45

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
User entered 'CA'	Lauren Arnett (b) (4)	10 Sep 2020 19:13:45
	(b) (4)	

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
User entered '91942'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 19:13:45

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:57:47
Un-reviewed for Safety.	System	23 Sep 2020 17:55:57
User entered 'US'	System	23 Sep 2020 17:55:57
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
User entered empty; reason for change Data Entry Error	Lauren Arnett (b) (4)	10 Sep 2020 19:17:53
User entered 'US' (non-conformant).	(b) (4)	
	System	10 Sep 2020 16:43:31

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
	(b) (4)	
User entered '5'	System	07 Nov 2020 00:14:22
User entered '4'	System	15 Oct 2020 14:15:10
User entered '3'	System	08 Oct 2020 13:57:59
User entered '2'	System	23 Sep 2020 17:55:57
User entered '1'	System	10 Sep 2020 16:43:31

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 12 Aug 2021 13:22:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
User entered '10/Sep/2020 12:43'	System	10 Sep 2020 16:43:31

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 12 Aug 2021 13:22:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
User entered 'I'	(b) (4), (b) (6)	10 Sep 2020 16:43:31

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'USA-US102-2020-MRNA-1273-P301000001'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
Amendment Manager: User entered 'Scott'	System	14 Sep 2020 21:58:34
User entered 'Jeffrey'	Lauren Arnett (b) (4)	10 Sep 2020 19:13:45
	(b) (4)	

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
User entered 'Overcash'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 19:13:45

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
Amendment Manager: User entered '5565 Grossmont Center Dr'	System	14 Sep 2020 21:58:34
User entered '5565 Grossmont Center Dr. BLD 2 Suite 1'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 19:13:45

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
User entered 'La Mesa'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 19:13:45

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
User entered 'CA'	Lauren Arnett (b) (4)	10 Sep 2020 19:13:45
	(b) (4)	

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
User entered '91942'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 19:13:45

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:57:47
Un-reviewed for Safety.	System	23 Sep 2020 17:55:57
User entered 'US'	System	23 Sep 2020 17:55:57
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
User entered empty; reason for change Data Entry Error	Lauren Arnett (b) (4)	10 Sep 2020 19:17:53
User entered 'US' (non-conformant).	(b) (4)	
	System	10 Sep 2020 16:43:31

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
	(b) (4)	
User entered '5'	System	07 Nov 2020 00:14:22
User entered '4'	System	15 Oct 2020 14:15:10
User entered '3'	System	08 Oct 2020 13:57:59
User entered '2'	System	23 Sep 2020 17:55:57
User entered '1'	System	10 Sep 2020 16:43:31

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 12 Aug 2021 13:22:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
User entered '23/Sep/2020 13:55'	System	23 Sep 2020 17:55:57

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 12 Aug 2021 13:22:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:57:47
User entered 'I'	(b) (4), (b) (6)	23 Sep 2020 17:55:57

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'USA-US102-2020-MRNA-1273-P301000001'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
Amendment Manager: User entered 'Scott'	System	14 Sep 2020 21:58:34
User entered 'Jeffrey'	Lauren Arnett (b) (4)	10 Sep 2020 19:13:45
	(b) (4)	

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
User entered 'Overcash'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 19:13:45

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
Amendment Manager: User entered '5565 Grossmont Center Dr'	System	14 Sep 2020 21:58:34
User entered '5565 Grossmont Center Dr. BLD 2 Suite 1'	Lauren Arnett (b) (4)	10 Sep 2020 19:13:45
	(b) (4)	

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
User entered 'La Mesa'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 19:13:45

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
User entered 'CA'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 19:13:45

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
User entered '91942'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 19:13:45

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:57:47
Un-reviewed for Safety.	System	23 Sep 2020 17:55:57
User entered 'US'	System	23 Sep 2020 17:55:57
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
User entered empty; reason for change Data Entry Error	Lauren Arnett (b) (4)	10 Sep 2020 19:17:53
User entered 'US' (non-conformant).	(b) (4)	
	System	10 Sep 2020 16:43:31

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
	(b) (4)	
User entered '5'	System	07 Nov 2020 00:14:22
User entered '4'	System	15 Oct 2020 14:15:10
User entered '3'	System	08 Oct 2020 13:57:59
User entered '2'	System	23 Sep 2020 17:55:57
User entered '1'	System	10 Sep 2020 16:43:31

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 12 Aug 2021 13:22:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
User entered '08/Oct/2020 13:57'	System	08 Oct 2020 13:57:59

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 12 Aug 2021 13:22:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 14:15:01
User entered 'I'	(b) (4), (b) (6)	08 Oct 2020 13:57:59

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'USA-US102-2020-MRNA-1273-P301000001'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
Amendment Manager: User entered 'Scott'	System	14 Sep 2020 21:58:34
User entered 'Jeffrey'	Lauren Arnett (b) (4)	10 Sep 2020 19:13:45
	(b) (4)	

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
User entered 'Overcash'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 19:13:45

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
Amendment Manager: User entered '5565 Grossmont Center Dr'	System	14 Sep 2020 21:58:34
User entered '5565 Grossmont Center Dr. BLD 2 Suite 1'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 19:13:45

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
User entered 'La Mesa'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 19:13:45

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
User entered 'CA'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 19:13:45

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
User entered '91942'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 19:13:45

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:57:47
Un-reviewed for Safety.	System	23 Sep 2020 17:55:57
User entered 'US'	System	23 Sep 2020 17:55:57
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
User entered empty; reason for change Data Entry Error	Lauren Arnett (b) (4)	10 Sep 2020 19:17:53
User entered 'US' (non-conformant).	(b) (4)	
	System	10 Sep 2020 16:43:31

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
	(b) (4)	
User entered '5'	System	07 Nov 2020 00:14:22
User entered '4'	System	15 Oct 2020 14:15:10
User entered '3'	System	08 Oct 2020 13:57:59
User entered '2'	System	23 Sep 2020 17:55:57
User entered '1'	System	10 Sep 2020 16:43:31

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 12 Aug 2021 13:22:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
User entered '15/Oct/2020 10:15'	System	15 Oct 2020 14:15:10

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 12 Aug 2021 13:22:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
Reviewed for Safety.	(b) (4)	07 Nov 2020 00:14:11
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:59:33
User entered '1'		15 Oct 2020 14:15:10

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'USA-US102-2020-MRNA-1273-P301000001'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:43:24
User entered 'No (N)'	System	10 Sep 2020 16:25:56

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
Amendment Manager: User entered 'Scott'	System	14 Sep 2020 21:58:34
User entered 'Jeffrey'	Lauren Arnett (b) (4)	10 Sep 2020 19:13:45
	(b) (4)	

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
User entered 'Overcash'	Lauren Arnett (b) (4)	10 Sep 2020 19:13:45
	(b) (4)	

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
Amendment Manager: User entered '5565 Grossmont Center Dr'	System	14 Sep 2020 21:58:34
User entered '5565 Grossmont Center Dr. BLD 2 Suite 1'	Lauren Arnett (b) (4)	10 Sep 2020 19:13:45
	(b) (4)	

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
User entered 'La Mesa'	Lauren Arnett (b) (4)	10 Sep 2020 19:13:45
	(b) (4)	

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
User entered 'CA'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 19:13:45

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
User entered '91942'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 19:13:45

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:59:33
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:57:47
Un-reviewed for Safety.	System	23 Sep 2020 17:55:57
User entered 'US'	System	23 Sep 2020 17:55:57
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:55:45
User entered empty; reason for change Data Entry Error	Lauren Arnett (b) (4)	10 Sep 2020 19:17:53
User entered 'US' (non-conformant).	(b) (4)	
	System	10 Sep 2020 16:43:31

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:22:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
	(b) (4)	
User entered '5'	System	07 Nov 2020 00:14:22
User entered '4'	System	15 Oct 2020 14:15:10
User entered '3'	System	08 Oct 2020 13:57:59
User entered '2'	System	23 Sep 2020 17:55:57
User entered '1'	System	10 Sep 2020 16:43:31

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 12 Aug 2021 13:22:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:26:44
User entered '06/Nov/2020 19:14'	System	07 Nov 2020 00:14:22

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 12 Aug 2021 13:22:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:04:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:26:44
User entered 'I'	(b) (4), (b) (6)	07 Nov 2020 00:14:22